NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* 1st as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 15. REVENUE

CHAPTER 1. DEPARTMENT OF REVENUE
ESTATE TAX SECTION

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R15-1-101	Amend
R15-1-102	Amend
R15-1-103	Repeal
R15-1-103	New Section
R15-1-104	Repeal
R15-1-104	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. §§ 42-1005, 42-4012

Implementing statute: A.R.S. §§ 42-4001 through 42-4102

3. The effective date of the rules:

September 22, 1999

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 4 A.A.R. 2130, July 31, 1998.
Notice of Proposed Rulemaking: 5 A.A.R. 554, February 26, 1999.

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Ernest Powell, Supervisor

Or

Jerry Skinner, Tax Analyst

Address: Tax Research and Analysis Section
Arizona Department of Revenue
1600 W. Monroe
Phoenix, AZ 85007

Telephone: (602) 542-4672

Fax: (602) 542-4680

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The rules provide guidance in the application of the Arizona estate tax. As a result of recent legislative changes and the Department's 5-year review of Chapter 1, the Department is proposing to repeal those rules where the parent statute has been repealed and to amend antiquated and repetitive rules. In addition, the Department proposes to amend the definition rule (R15-1-101) to remove portions of the rule that are not definitional. The Department is proposing 2 new sections that contain the non-definitional information being removed from the definition rule.

7. Reference to any study that the agency relied on and its evaluation of or justification for final rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None.

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:

Not applicable.

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

It is expected that the benefits of the rules will be greater than the costs. The repeal of 2 of these rules will benefit the public by eliminating rules that are contrary to statute. The amendment and addition of the balance of these rules will benefit the public by eliminating repetitive and obsolete language and by moving non-definitional language out of the definition rule. The Department will incur the costs associated with the rulemaking process. Taxpayers are not expected to incur any expense in the addition, repeal or amendment of these rules.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

In R15-1-101(2), "Cecurrency" is replaced with "Currency ~~currency~~.

In addition, based on the review performed by the staff of the Governor's Regulatory Review Council, the department made various nonsubstantive grammatical and formatting changes.

11. A summary of the principal comments and the agency response to them:

The department did not receive any written or verbal comments on the rule action after the publication of the rule-making in the Notice of Proposed Rulemaking.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None.

13. Incorporations by reference and their location in the rules:

None.

14. Was the rule previously adopted as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 15. REVENUE

CHAPTER 1. DEPARTMENT OF REVENUE
ESTATE TAX SECTION

ARTICLE 1. GENERAL PROVISIONS

Section
R15-1-101. Definitions ~~Administration and definitions~~
R15-1-102. Partnership Interest ~~interest~~
~~R15-1-103.~~ ~~Safe deposit boxes~~
R15-1-103. Interests Involving Real Property
~~R15-1-104.~~ ~~Consents~~
R15-1-104. Determination of Decedent's Domicile

ARTICLE 1. GENERAL PROVISIONS

R15-1-101. Definitions ~~Administration and definitions~~

~~A.~~ ~~Definitions~~

In addition to the definitions provided in A.R.S. § 42-4001, the following definitions apply to this Chapter.

1. ~~A resident shall be a person who is domiciled in Arizona.~~ "Domicile" means ~~shall be~~ the place where a person has a true, fixed, permanent home. It is the place to which the person intends to return whenever absent. ~~with which the person has a settled connection for legal purposes, either because the person's home is there or because the place is assigned to the person by law. Evidence of a person's intent as to domicile shall include~~:
   a. ~~Ownership or lease and occupancy of dwelling.~~
   b. ~~Place of transaction of business or employment.~~

~~c. Registration as voter.~~
~~d. Place of filing of federal income tax return.~~
~~e. Declaration of place of residence in will.~~
~~f. Recitals in deeds and legal documents.~~
~~g. Written and oral declarations generally.~~
~~h. Situs of bank accounts and securities.~~
~~i. Membership in church, clubs, lodges, societies.~~
~~j. Automobile registration and driver's license.~~
~~k. Claiming or filing homestead exemptions.~~
~~l. Registration in public or private schools of minor children living with their parents.~~
~~Any of the foregoing evidentiary factors shall not be conclusive and the Estate Tax Section of the Arizona Department of Revenue shall determine domicile under all circumstances applicable.~~

~~2.~~ ~~"Personal property" shall include all property that is not real property.~~

2.~~3.~~ "Intangible personal property" means personal ~~shall include currency, bank accounts, franchises, stocks and bonds, credits, chooses in action, business goodwill and all other~~ property that represents a right or evidence of value such as bonds, copyrights, currency, franchises, patents, stocks, and trademarks. ~~rather than a physical object. For the purpose of this definition,~~ Currency ~~currency~~ does ~~shall~~ not include money ~~that was~~ held by the decedent for its numismatic value or as jewelry.

3. "Personal property" means all property that is not real property.

4. "Tangible personal property" means ~~shall include~~ personal property that has a physical form and substance ~~can be felt or touched~~ and is not intangible.

~~**B.** Mortgages on real property, land sale contracts and land trusts: mortgages are not an interest in land, but a lien on land and are, therefore, personal property.~~

~~1. A lease is an ownership right or interest in land and shall be classified as real property.~~

~~2. A contract to convey land constitutes an equitable conversion so that the seller's interest shall be personal property and the buyer's interest shall be real property.~~

~~3. Land trust agreements, subdivision or similar trusts, commonly employed by Arizona trust companies which expressly provide that the interest of the beneficiary of the trust shall be deemed to be personal property with no right, title or interest or to any portion or specific part of the real estate, but only an interest in the earnings or proceeds, then the interest of the beneficiary shall be personal property. When a real estate syndicate agreement or trust provides that the beneficial interest consists of an undivided interest in the land, the interest shall be taxable as real property.~~

~~**C.** The Arizona estate tax return shall be filed with the estate tax return on or before the date the federal estate tax return is required to be filed.~~

R15-1-102. Partnership Interest ~~interest~~

The Department shall classify a decedent's partnership interest as follows:

1.~~**A.**~~ If the partnership business is continued after the death of a partner, ~~When,~~ pursuant to the Uniform Partnership Act (A.R.S. §§ 29-201 through 29-243~~Chapter 2, Title 29, A.R.S.~~) or the partnership agreement, ~~the partnership business is continued after the death of a partner,~~ the partnership interest of the decedent ~~partner~~ is classified as intangible personal property ~~and taxable in accordance with the residence of the decedent~~. ~~The value of the partnership interest of a resident decedent is includible in the gross estate regardless of the business situs of the partnership or the kind of property owned by the partnership.~~

~~**B.** The value of the partnership interest shall include goodwill ascertained when practicable and equitable by capitalizing partnership income.~~

2.~~**C.**~~ If ~~When~~ the partnership is dissolved upon the death of a partner and the assets distributed in kind, the determination of the Arizona estate is based on the classification of each asset, whether real property, tangible personal property, or intangible personal property. ~~nature of the partnership assets determines whether they are includible in the state of residence or the state of physical location.~~

~~**R15-1-103. Safe deposit boxes**~~ **Repealed**

~~**A.** The safe depository, bailee or lessor from whom the safe deposit box, receptacle or envelope is rented shall notify the Estate Tax Section of the death of any person having access to such box or receptacle, and shall not, except as hereinafter provided, deliver any of the contents thereof without permission of the Estate Tax Section, granted after inventory has been received by the Estate Tax Section.~~

~~**B.** Upon the death of any person in whose name any box or receptacle is rented or having access to any box or receptacle held or rented in a corporate name, or in the name of any other business entity, or in any name other than that of the decedent having such access, the procedure herein prescribed for inventory and report to the Estate Tax Section shall be followed.~~

~~**C.** The original inventory of a safe deposit box or receptacle shall be sent to the Estate Tax Section, with copies retained by the bank and representative of the decedent.~~

~~**D.** The inventory and report to the Estate Tax Section shall contain the following information:~~
- ~~1. Name and address of the safe depository.~~
- ~~2. The name under which the box has been held, if different from that of the name of the decedent having access thereto, and the name of the decedent.~~
- ~~3. Date of inventory and signatures of the persons present at the time the inventory is taken.~~
- ~~4. The contents shall be listed as follows:~~
  - ~~a. Life insurance policies -- list name of company, amount, to whom payable and ownership, if shown.~~
  - ~~b. Fire insurance policies -- list as various fire insurance policies.~~
  - ~~c. Deeds to real estate -- short description and address of property, if shown.~~
  - ~~d. Mortgages and notes -- list dates, amounts, to whom payable, and the maker.~~
  - ~~e. Stocks, common and preferred -- number of shares, name of company, name of owner.~~
  - ~~f. United States Savings Bonds -- group the various series, and show individual bond amounts, and to whom payable. Serial numbers need not be listed.~~
  - ~~g. Bearer bonds -- such as U.S. Treasury or various municipal bonds -- should be listed and described.~~
  - ~~h. Wills -- show date of will and name of Personal Representative.~~
  - ~~i. Currency -- list amount.~~
  - ~~j. Jewelry -- number and general description of pieces.~~
  - ~~k. Keepsakes without any apparent monetary value -- may be listed as keepsakes.~~
  - ~~l. Miscellaneous papers without any apparent monetary value -- may be so listed without any further description.~~
  - ~~m. Sealed envelopes indicating that they contain property or information for someone other than the box holder or the individual having access to the box -- such envelopes should not be opened but must be listed as a sealed envelope and as being the property of the person named on the sealed envelope.~~
  - ~~n. In the case of an inventory of a box, receptacle or envelope retained in a corporate name where the deceased is listed on the bank's records as an officer of the corporation -- the inventory shall not list in detail such property and items as clearly on their face show that they are the property of the corporation and not the property of the deceased, but such property and items shall be listed generally as "corporate property".~~

~~**E.** The depository may without notice to or consent of the Estate Tax Section deliver such of the items as may be found in a safe deposit box, receptacle or envelope, as follows:~~
- ~~1. Wills -- to the personal representative of the deceased named therein or to the clerk of the superior court.~~
- ~~2. Insurance policies on the life of the deceased -- to the beneficiaries named therein.~~
- ~~3. Sealed envelopes described in subparagraph (D)(4)(m) -- to the person whose name appears thereon or, if he is deceased, to his personal representative.~~

R15-1-103. Interests Involving Real Property

The Department shall classify interests involving real property as follows:
1. A mortgage on real property is a lien on the property and is classified as intangible personal property.
2. A contract to convey real property constitutes an equitable conversion. If the decedent was the seller, the decedent's interest is classified as intangible personal property. If the decedent was the buyer, the decedent's interest is classified as real property.
3. A lease of real property is an interest in land and is classified as real property.
4. A decedent's beneficial interest under a land trust agreement is classified in accordance with the provisions of the trust agreement. If the agreement provides that the beneficial interest consists of an undivided interest in the land, the interest is classified as real property. If the agreement provides that the beneficial interest consists of an interest in the earnings or proceeds, with no right, title, or interest in any portion of the land, the interest is classified as intangible personal property.

~~R15-1-104. Consents~~ Repealed

~~**A.** Transfers of stock in an Arizona corporation or a corporation authorized to do business in Arizona held, solely or jointly, by a decedent who was a resident of Arizona shall be consented to by the Estate Tax Section, upon application in writing.~~

~~**B.** The Estate Tax Section shall, upon application in writing, consent to the release of assets belonging to a decedent who was a resident or a nonresident in the custody of any person, safe deposit company, trust company, corporation, bank or other institution located in Arizona.~~

~~**C.** Individual bank deposits of ten thousand dollars or less do not require the consent of the Estate Tax Section.~~

~~**D.** A charge of $2.00 shall be made for each consent to transfer stock of a resident decedent, with the exception of one consent per decedent.~~

R15-1-104. Determination of Decedent's Domicile

The Department shall consider all circumstances including the following in determining a decedent's domicile:
1. Ownership or lease and occupancy of dwelling;
2. Place of transaction of business or employment;
3. Registration as voter;

4. Place of filing of federal income tax return;
5. Declaration of place of residence in will;
6. Recitals in deeds and legal documents;
7. Written and oral declarations;
8. Situs of bank accounts and securities;
9. Membership in church, clubs, lodges, or societies;
10. Automobile registration and driver's license;
11. Claiming or filing homestead exemptions; and
12. Registration in public or private schools of minor children living with their parents.

NOTICE OF FINAL RULEMAKING

TITLE 15. REVENUE

CHAPTER 2. DEPARTMENT OF REVENUE
INCOME AND WITHHOLDING TAX SECTION

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R15-2-401	Amend
R15-2-403	Amend
R15-2-431	Repeal
R15-2-432	Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. §§ 42-1005

Implementing statute: A.R.S. §§ 43-401, 43-403, and 43-432

3. The effective date of the rules:

September 22, 1999

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 2 A.A.R. 4824, November 29, 1996.
Notice of Proposed Rulemaking: 5 A.A.R. 1400, May 14, 1999.

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Ernest Powell, Supervisor

Address: Tax Research and Analysis Section
Arizona Department of Revenue
1600 W. Monroe
Phoenix, AZ 85007

Telephone: (602) 542-4672

Fax: (602) 542-4680

6. An explanation of the rule, including the agency's reasons for initiating the rule:

The rules provide guidance regarding Arizona income tax withholding. The Department is proposing to amend the rules to incorporate legislative changes, remove obsolete and repetitive language, and to conform to current rulemaking guidelines. In addition, the Department is proposing to repeal R15-2-431, which is an obsolete reference to a rule that was previously repealed.

7. Reference to any study that the agency relied on and its evaluation of or justification for final rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

None.

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:

Not applicable.

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

It is expected that the benefits of the rules will be greater than the costs. The amendment of these rules will benefit the public by eliminating repetitive and obsolete language and by providing guidance regarding recent legislative changes. The repeal of R15-2-431 will benefit the public by eliminating a reference to a rule that was previously repealed. The Department will incur the costs associated with the rulemaking process. Taxpayers are not expected to incur any expense in the repeal or amendment of these rules.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Due to a publishing error, the example in R15-2-401(A)(2) contained a minor formatting error when it was published in the *Arizona Administrative Register.* The formatting error has been corrected in the final rulemaking.

The Notice of Proposed Rulemaking submitted to the Secretary of State's Office showed strike-outs through various words in R15-2-401(E). However, due to a publishing error, the strike-outs were not shown when it was published in the *Arizona Administrative Register.* The strike-outs are included in the final rulemaking.

In the Notice of Proposed Rulemaking submitted to the Secretary of State's Office, the beginning of the example in R15-2-403(A)(3) read "For example, casual ~~Such~~ labor includes". However, due to a publishing error, the beginning of the example in R15-2-403(A)(3) read "For example, casual Such labor includes". The publishing error is corrected in the final rulemaking.

In addition, based on the review performed by the staff of the Governor's Regulatory Review Council, the department made various nonsubstantive grammatical and formatting changes.

11. A summary of the principal comments and the agency response to them:

The Department did not receive any written or verbal comments on the rule action after the publication of the rulemaking in the Notice of Proposed Rulemaking.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None.

13. Incorporations by reference and their location in the rules:

None.

14. Was the rule previously adopted as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 15. REVENUE

CHAPTER 2. DEPARTMENT OF REVENUE
INCOME AND WITHHOLDING TAX SECTION

ARTICLE 4. WITHHOLDING

Sections

ARTICLE 4. WITHHOLDING

R15-2-401. Payment Schedule; Rates; Election by Employee ~~Rates of withholding; election by employee~~

A. ~~At the end of each calendar quarter, the employer shall recompute its quarterly average and file according to the due dates established by law.~~ An employer shall determine its Arizona withholding payment schedule for each calendar quarter by calculating the average amount of Arizona income taxes withheld in the 4 preceding calendar quarters. The employer shall calculate this average at the beginning of each calendar quarter by adding the actual amount withheld in each of the 4 preceding calendar quarters and then dividing that sum by 4.

1. If the average amount of Arizona income taxes withheld in the 4 preceding calendar quarters does not exceed $1,500, the employer shall make its Arizona withholding payments on a quarterly basis.
   Example:
   An employer determines its Arizona withholding payment schedule for the 4th calendar quarter of 1999 as follows:

3rd quarter of 1999 withholding	$1,100
2nd quarter of 1999 withholding	1,600
1st quarter of 1999 withholding	1,000
4th quarter of 1998 withholding	1,200
Total withholding	$4,900
Divide by	4
Average withholding	$1,225

The 4 quarter average of Arizona income taxes withheld does not exceed $1,500. Therefore, the employer shall make its Arizona withholding payments on a quarterly basis.

2. If the average amount of Arizona income taxes withheld in the 4 preceding calendar quarters exceeds $1,500, the employer shall make its Arizona withholding payments at the same time as the employer is required to make its federal withholding deposits.

Example:

An employer determines its Arizona withholding payment schedule for the 3rd calendar quarter of 1999 as follows:

2nd quarter of 1999 withholding	$1,800
1st quarter of 1999 withholding	1,400
4th quarter of 1998 withholding	1,900
3rd quarter of 1998 withholding	1,300
Total withholding	$6,400
Divide by	4
Average withholding	$1,600

The 4 quarter average of Arizona income taxes withheld exceeds $1,500. Therefore, the employer shall make its Arizona withholding payments at the same time as its federal withholding deposits.

B. An employer that purchases an existing business shall determine its Arizona withholding payment schedule for each calendar quarter by calculating the average amount withheld in the 4 preceding calendar quarters as follows:

1. For the 1st quarter of withholding, the employer shall calculate the previous owner's average amount of Arizona income taxes withheld in the 4 preceding calendar quarters.
2. For the 2nd through 4th quarters of withholding, the employer shall calculate the average amount withheld in the 4 preceding calendar quarters by combining its prior quarters of withholding with the previous owner's quarters of withholding.
3. For subsequent quarters of withholding, the employer shall add the amounts it withheld in the 4 preceding calendar quarters and then divide that sum by 4.

C. A newly formed business shall determine its Arizona withholding payment schedule as follows:

1. For the 1st quarter of withholding, the employer shall make its Arizona withholding payments on a quarterly basis.
2. For the 2nd quarter of withholding, the employer shall determine its Arizona withholding payment schedule based on the amount withheld in the 1st quarter of withholding.
3. For the 3rd quarter of withholding, the employer shall determine its Arizona withholding payment schedule by adding the amounts withheld in the 1st and 2nd quarters and dividing by 2.
4. For the 4th quarter of withholding, the employer shall determine its Arizona withholding payment schedule by adding the amounts withheld in the 1st, 2nd, and 3rd quarters and dividing by 3.
5. For subsequent quarters of withholding, the employer shall determine its Arizona withholding payment schedule by adding the amounts withheld in the 4 preceding calendar quarters and dividing by 4.

~~**B.** If the employer has no historical data for four full consecutive quarters upon which to determine the lawful due dates of his payments, he shall determine the due dates for payments under this subsection. The due dates for the payments to the Department shall conform to the federal deposit requirements whenever the quarterly average for state withholding exceeds $1500.~~

~~1. Except as provided in R15-2-401(B)(5) a newly formed business or a new employer shall remit payment for the first quarter that it withholds taxes on or before the last day of the first month of the next calendar quarter.~~

~~2. If the employer's first payment under R14-2-401(B)(1) does not represent a full quarter of withholding, the employer shall determine its quarterly average for the first full quarter by annualizing the amount withheld in the first partial quarter and dividing by four.~~

~~3. During the second full quarter an employer shall consider the quarterly average to be the amount collected for the first full quarter of withholding. The employer shall determine the quarterly average in subsequent full quarters by adding the amounts withheld during the prior full quarters and dividing by the number of full quarters of withholding activity.~~

D.~~4.~~ If 2 ~~two~~ or more employers consolidate their business activities to form 1 entity, ~~one enterprise,~~ the new employer shall determine its Arizona withholding payment schedule based on the ~~they shall use their~~ combined withholding of the prior employers for the preceding 4 ~~four full~~ calendar quarters. ~~to determine their quarterly average.~~

Any ~~If one of the~~ prior employer ~~employers~~ with ~~has~~ fewer than 4 ~~four~~ full ~~calendar~~ quarters of withholding activity~~,~~ ~~it~~ shall annualize the amounts withheld~~,~~ and divide by 4. ~~four and~~ The new employer shall determine its Arizona withholding payment schedule by combining this amount ~~combine this quotient~~ with the quarterly averages ~~average~~ of the other prior employers ~~employer~~ with 4 full quarters of withholding activity.

5. ~~An employer who purchases an existing business shall use the previous owner's quarterly average to determine the due dates for payments.~~

E.~~C.~~ ~~The~~ employer shall complete ~~submit~~ the quarterly reconciliation required by ~~pursuant to~~ A.R.S. § 43-401 ~~upon~~ by filing the quarterly tax return ~~reconciliation form~~ prescribed ~~supplied~~ by the Department.

F. For calendar years beginning after December 31, 1997, an employer may make its Arizona withholding payments on an annual basis if all of the following conditions are met:

1. The employer has established a history of withholding activity by filing the quarterly tax return required by subsection (E) for at least the 4 preceding calendar quarters.
2. The employer's withholding liability was an amount greater than zero for at least 1 of the 4 preceding calendar quarters.
3. The average amount of Arizona income taxes withheld by the employer in the 4 preceding calendar quarters does not exceed $200. The employer will meet this average withholding requirement if the total amount withheld in the 4 preceding calendar quarters is $800 or less.
4. The employer has timely filed the quarterly tax return and has timely made its Arizona withholding payments for at least 3 of the 4 preceding calendar quarters.
5. The employer has filed the quarterly tax return for all preceding calendar quarters and does not have a balance due (tax, penalty, or interest) for any preceding calendar quarter.
6. The employer has filed the annual reconciliation tax return required by A.R.S. § 43-412 for all preceding calendar years and has timely filed the annual reconciliation tax return for the preceding calendar year.

G. An employer that makes its Arizona withholding payments on a annual basis under subsection (F), shall file the annual tax return required by A.R.S. § 43-401 on the form prescribed by the Department. The form shall contain all the information required by A.R.S. 43-412. The employer shall make its annual Arizona withholding payment by February 28 of the year following the year for which the report was made.

H. An employer that makes its Arizona withholding payments on a annual basis under subsection (F), may continue to make its Arizona withholding payments on an annual basis for the succeeding calendar year if both of the following conditions are met:

1. The average amount of Arizona income taxes withheld by the employer in the 4 preceding calendar quarters does not exceed $200.

   Example 1:

   An employer determines whether the average amount of Arizona income taxes withheld in the 4 preceding calendar quarters does not exceed $200 as follows:

4th quarter of 1999 withholding	$200
3rd quarter of 1999 withholding	200
2nd quarter of 1999 withholding	250
1st quarter of 1999 withholding	150
Total withholding	$800
Divide by	4
Average withholding	$200

   The average amount of Arizona income taxes withheld in the 4 preceding calendar quarters does not exceed $200. Therefore, the employer may make its Arizona withholding payments on an annual basis for the succeeding calendar year, if the employer also meets the condition stated in subsection (H)(2).

   Example 2:

   An employer determines whether the average amount of Arizona income taxes withheld in the 4 preceding calendar quarters does not exceed $200 as follows:

4th quarter of 1999 withholding	$200
3rd quarter of 1999 withholding	400
2nd quarter of 1999 withholding	250
1st quarter of 1999 withholding	150
Total withholding	$1,000
Divide by	4
Average withholding	$250

   The average amount of Arizona income taxes withheld in the 4 preceding calendar quarters exceeds $200. Therefore, the employer may not make its Arizona withholding payments on an annual basis for the succeeding calendar year.

2. The employer has timely filed the annual tax return and has timely made its annual Arizona withholding payment as prescribed by subsection (G) for the preceding calendar year.

I. If the employer does not meet the conditions prescribed by subsection (H):
1. The employer shall determine its Arizona withholding payment schedule for succeeding calendar quarters as prescribed by subsection (A); and
2. The employer shall file the quarterly tax return for succeeding calendar quarters as prescribed by subsection (E).

J.D. An employer ~~Employers~~ shall determine the applicable rate ~~rates~~ of withholding for each employee as follows:
1. If ~~The election of a ten percent state withholding rate by~~ an employee whose annual compensation is ~~who earns a base salary of~~ less than $15,000 ~~annually~~ elects the minimum withholding rate, that rate shall apply ~~govern the deduction for withholding~~ until 1 ~~one~~ of the following situations occurs:
   a. Until the employee has 12 full months of work history with the employer, the employer shall determine the employee's annualized compensation at the end of each month. The employer may use any method of annualization that accurately reflects the employee's annual compensation. If the employer determines that the employee's annualized compensation is $15,000 or more, the employer shall adjust the employee's rate of withholding beginning the next full pay period following the determination. The employer shall adjust the rate to the minimum rate prescribed by A.R.S. § 43-401, unless the employee elects a higher prescribed rate of withholding for the employee's annual compensation. The employer shall apply the minimum rate of withholding until the employee has been employed for 12 full months, unless the employee elects a higher prescribed rate of withholding for the employee's annual compensation. After 12 full months of employment, the employer shall determine the rate under subsection (J)(1)(b);
   b.~~a.~~ If the employee has 12 full months of work history with the employer, the employer shall determine the employee's ~~his~~ total compensation for the 12-month period. If the records for that period show that the employee earned $15,000 or more, the employer shall adjust the rate of withholding ~~to 15 percent~~ beginning the next full pay period following the determination. The employer shall adjust the rate to the minimum rate prescribed by A.R.S. § 43-401, unless the employee elects a higher prescribed rate of withholding for the employee's annual compensation. The employer shall apply this ~~This~~ rate of withholding ~~shall continue~~ through the end of the calendar year, unless the employee elects a higher prescribed rate of withholding for the employee's annual compensation. At the end of that calendar year and at the end of each succeeding calendar year, the employer shall redetermine the employee's total annual compensation. If the employee's annual compensation for the preceding year changes the employee's ~~his~~ rate of withholding, the rate change shall begin the next full pay period following the determination; or
   ~~b. If the employee has less than 12 full months of work history with the employer, the employer shall determine the employee's annualized compensation at the end of the month. If the employer determines that the employee's annualized compensation is equal to or greater than $15,000, the employer shall adjust the employee's rate of withholding to 15 percent beginning the next full pay period following the determination. The rate shall remain at 15 percent until the employee has been employed for 12 full months. After 12 full months of employment, the employer shall determine the rate in accordance with R15-2-401(D)(1)(a); or~~
   c. If the employee receives a salary increase that makes the employee's ~~his~~ annualized compensation ~~equal to or greater than~~ $15,000 or more, the employer shall adjust the employee's rate of withholding to the minimum rate prescribed by A.R.S. § 43-401, ~~15 percent~~ beginning the next full pay period following the receipt of the increase by the employee.
2. An employee who has elected a ~~to state~~ withholding rate higher than the minimum prescribed withholding rate ~~of 15 or 20 percent~~ may later elect to reduce the rate to a lower prescribed rate for the employee's annual compensation. ~~ten percent if his annual compensation is not equal to or greater than $15,000.~~

R15-2-403. Employment Excluded from Withholding ~~Excluded employment~~

A. An employer shall not withhold Arizona income taxes from: ~~Section 43-403 excludes the following types of employment from the withholding provisions of the Act:~~
~~1. Wages paid for active service in the military or naval forces of the United States.~~
1.~~2.~~ Wages paid to an employee ~~employees~~ of a common carrier when that employee is a nonresident ~~non-resident~~ of Arizona and regularly performs services inside and outside the state.
2.~~3~~ Wages paid for domestic service in a private home. ~~house.~~
Generally, service of a household nature in or about a private home ~~house~~ includes services rendered by cooks, maids, butlers, valets, ~~laundresses, furnace men,~~ housekeepers, gardeners, ~~gardener,~~ caretakers, ~~footmen,~~ companions, child-care providers (baby-sitter, governess, nanny), grooms, and chauffeurs of automobiles for family use. If the home ~~house~~ is used ~~utilized~~ primarily for the purpose of supplying board or lodging to the public as a business enterprise, it ceases to be a private home. ~~house and the remuneration paid for services performed is not expected.~~ The compensation ~~remuneration~~ paid for the services listed ~~enumerated~~ above is not exempt from withholding ~~within the exception~~ if performed in or about rooming or lodging houses, boarding houses, clubs, hotels, motels, bed-and-breakfasts, hospitals, charitable ~~eleemosynary~~ institutions, or commercial offices or establishments. Services that are not ordinarily part of household duties and that involve the use of skilled or specialized training are not domestic services. Compen-

sation ~~Remuneration~~ paid for services performed as a private secretary even though performed in the employer's home ~~house~~ is not exempt from withholding. ~~within the exception.~~

3.~~4~~ Wages paid by employers ~~other than corporations~~ for casual labor not in the course of the employer's trade or business. "Casual labor not in the course of the employer's trade or business" means services that do not promote or advance the trade or business of the employer. The term does not include services performed for a corporation. For example, casual ~~Such~~ labor includes ~~would include~~ the labor performed by a carpenter employed by an individual to do incidental work on the individual's ~~his~~ house. If that ~~However, if such an~~ individual employed a carpenter to do incidental work in a factory operated by the ~~an~~ individual, the work would be in the course of the individual's trade or business. The compensation ~~and the remuneration~~ paid for that labor is not exempt from withholding. ~~exempted.~~ Seasonal employment of sales clerks during any peak sales periods of a business ~~the Christmas rush for instance~~ is ~~not~~ subject to withholding. ~~exempted employment. Remuneration paid for casual labor performed for a corporation is deemed to be in the course of the trade or the business of the corporation and therefore, is subject to withholding.~~

4.~~5~~ Wages paid for part-time or seasonal ~~Seasonal~~ agricultural labor.

a. ~~Withholding tax is not required to be withheld on wages~~ Wages paid to part-time or seasonal employees whose services to the employer consist solely of labor in connection with the planting, cultivating, harvesting, or field packing of seasonal agricultural crops are not subject to withholding.~~, except those~~ Wages paid to employees whose principal duties are to operate any mechanically driven device in these agricultural ~~such~~ operations are subject to withholding.

An employee is a part-time ~~A "part-time"~~ or seasonal agricultural employee if: ~~is construed to mean~~

a. The employer hires the employee ~~an individual hired~~ to help ~~assist~~ in 1 ~~one~~ of the steps in the development of a seasonal agricultural crop;

b. The employee does not perform any other services for ~~not otherwise engaged by~~ the same employer; and

c. The employee understands, at the date of employment, ~~with the understanding~~ that the employee's job will end ~~his employment will be terminated~~ on or before the completion of that step. ~~Withholding tax is required to be withheld on the entire wages paid to regular farm employees, and those whose principal duties are to operate mechanically driven devices, even though they are engaged in planting, cultivating, or harvesting crops as a part of their duties.~~

b. ~~Withholding tax is required to be withheld on wages paid to seasonal employees in the activities of canning and other food processing, logging, sheep shearing, etc., as they are not exclusively in connection with seasonal agricultural crops.~~

c. ~~Withholding tax is required to be withheld on wages paid in such agricultural activities as the care of poultry or livestock, dairy farming, etc., as they are not in connection with the planting, cultivating, or harvesting of seasonal agricultural crops.~~

6. ~~The above enumerated exempt occupations are exclusive and all other payments of wages are subject to withholding. However, the withholding of the tax will never be required on the payment of wages to employees if federal income tax is not required to be withheld.~~

B. Wages paid to a nonresident of Arizona engaged in any phase of motion picture production are not subject to withholding if the employee qualifies for a credit for taxes paid to the employee's state of residency or domicile. Before payment of the wages is due, the employer shall apply for an exemption by having the employee complete the withholding exemption certificate prescribed by the Department. The employer shall submit the completed certificate for each employee with the next quarterly return required by R15-2-401(E).

R15-2-431. ~~Amounts withheld (reference R15-2-503)~~

R15-2-432. Refund of Excess Withholding ~~excess withholding~~

If ~~In the case of the death of~~ a refund for an overpayment of income tax withheld is payable to a deceased taxpayer, ~~husband or wife or both when a joint return has been filed for the taxable year, or of a single person, and a refund is claimed because of an overpayment of income tax withheld, it is necessary that~~ the surviving spouse or other claimant shall attach the form prescribed by the Department ~~a notarized statement~~ to the deceased taxpayer's income tax return to establish the claimant's right to ~~so that~~ the refund. ~~may be issued in the name of the claimant. The statement shall designate the name and date of death of the deceased taxpayer and the name and address of the claimant.~~

NOTICE OF FINAL RULEMAKING

TITLE 15. REVENUE

CHAPTER 3. DEPARTMENT OF REVENUE
LUXURY TAX SECTION

PREAMBLE

1. Sections Affected **Rulemaking Action**

R15-3-401	Amend
R15-3-402	Amend
R15-3-403	Repeal
R15-3-403	New Section
R15-3-404	Repeal
R15-3-405	Repeal
R15-3-406	Amend
R15-3-407	Amend
R15-3-408	Amend
R15-3-409	Repeal
R15-3-410	Amend

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 42-1005 and 42-3004.

Implementing statutes: A.R.S. §§ 1-218, 4-243.01, 42-2003, 42-3008, 42-3010, 42-3052, 42-3153, 42-3351 through 42-3355.

3. The effective date of the rules:

September 22, 1999

4. A list of all previous notices appearing in the Register addressing the final rule:

Notice of Rulemaking Docket Opening: 4 A.A.R. 1412, June 19, 1998.
Notice of Proposed Rulemaking: 5 A.A.R. 1156, April 23, 1999.
Notice of Proposed Rulemaking: 5 A.A.R. 1274, May 7, 1999.

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Jaimie Lee, Tax Analyst

Address: Tax Research and Analysis Section
Arizona Department of Revenue
1600 West Monroe
Phoenix, AZ 85007

Telephone: (602) 542-4672

Fax: (602) 542-4680

6. An explanation of the rule, including the agency's reasons for initiating the rule:

These rules provide additional guidance regarding the tax return filing requirements by liquor wholesalers and manufacturers for luxury tax purposes. Since the time of the rules' adoption, the statutes relating to the tax return filing requirements by liquor wholesalers and manufacturers have been amended and the Department has revised the tax return forms. Due to these changes and the Department's 5-year review of Chapter 3, which was approved at the June 2, 1998, meeting of the Governor's Regulatory Review Council, the Department proposes to amend or repeal these rules because the rules are obsolete, repetitious or inconsistent with statutory provisions. The Department also proposes to add a new rule as a result of legislative changes.

7. Reference to any study that the agency proposes to rely on and its evaluation of or justification for the final rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable.

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:

Not applicable.

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

It is expected that the benefits of the rules will be greater than the costs. The repeal of R15-3-403 through R15-3-405 and R15-3-409 will benefit the public by eliminating repetitive or obsolete rules that no longer serve their intended purpose. The amendment of R15-3-401, R15-3-402, R15-3-406, and the addition of R15-3-403 will benefit the public by providing additional guidance regarding tax return filings. In addition, the amendment of R15-3-407, R15-3-408, and R15-3-410 will benefit the public by providing clearer and more concise information regarding the filing of tax returns. The Department will incur the costs associated with the rulemaking process. Taxpayers are not expected to incur any expense in the amendment of these rules.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Due to publishing errors in the Notice of Proposed Rulemaking that was printed in the *Arizona Administrative Register* (Volume 5, Issue #19, Page 1274, dated May 7, 1999), the comma after "primary source of supply" in the 1st line of R15-3-407 is stricken in this proposed final version of R15-3-407. In addition, R15-3-408 in the Notice of Proposed Rulemaking contained a reference to "the Department" following "A.R.S. § 4-243.01" which is not stricken in the version of R15-3-408 that is submitted in this rulemaking package.

The proposed final version of these rules contains minor nonsubstantive grammatical changes which were recommended by the Governor's Regulatory Review Council staff. Please note that the proposed final version of R15-3-402 specifies that spirituous liquor wholesalers shall report the monthly quantity of spirituous liquors received. This filing requirement was omitted in the version of R15-3-402 that was published in the Notice of Proposed Rulemaking. However, this filing requirement has always been included in the tax forms and thus, is not a substantial change to the tax return filing requirements for spirituous liquor wholesalers.

11. A summary of the principal comments and the agency response to them:

The Department did not receive any written or verbal comments on the rule action after the publication of the rulemaking in the Notice of Proposed Rulemaking.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None.

13. Incorporations by reference and their location in the rules:

None.

14. Was the rule previously adopted as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 15. REVENUE

CHAPTER 3. DEPARTMENT OF REVENUE
LUXURY TAX SECTION

ARTICLE 4. LIQUOR

Section

R15-3-401. Tax Return Filing Requirements – Vinous or Malt Liquor Wholesaler ~~Wholesaler's return of vinous and malt liquor purchased~~
R15-3-402. Tax Return Filing Requirements – Spirituous Liquor Wholesaler ~~Wholesaler's return of spirituous liquor sold~~
~~R15-3-403. Distiller's and manufacturer's report~~ Repealed
R15-3-403. Tax Return Filing Requirements – Domestic Microbrewery, Domestic Farm Winery, Domestic Cider Producer, or Beer Manufacturer
R15-3-404. ~~Wholesaler's claims for credit or refunds on unsaleable liquor~~ Repealed
R15-3-405. ~~Powdered distilled spirits~~ Repealed
R15-3-406. Metric Conversion ~~conversion~~
~~R15-3-407. Primary~~ Source ~~source~~ of Supply – Failure ~~failure~~ to Report ~~report~~ Sales to Arizona Wholesalers ~~by primary source~~
~~R15-3-408.~~ Arizona Wholesaler – Failure to Report Purchases from a Primary Source of Supply ~~Primary source – failure to~~

~~report by Arizona wholesalers~~
R15-3-409. ~~Common bond~~ Repealed
~~R15-3-410. Failure to~~ File ~~make~~ a Return ~~return, failure to~~ or Pay ~~pay~~ Tax ~~tax~~

ARTICLE 4. LIQUOR

R15-3-401. Tax Return Filing Requirements – Vinous or Malt Liquor Wholesaler ~~Wholesaler's return of vinous and malt liquor purchased~~
On or before the statutory deadline each month, each wholesaler of vinous or malt liquor shall file a return on a form prescribed by the Department. The return shall show the following:

1. Taxpayer's name, mailing address, business address, liquor license number, and identification number;
2. The itemized quantities of vinous and malt liquors purchased during the month the tax accrued, listed by supplier and invoice number;
3. The itemized quantities of tax-free sales of vinous and malt liquors during the month the tax accrued, listed by purchaser and invoice number;
4. The itemized quantities of out-of-state sales of vinous and malt liquors during the month the tax accrued, listed by purchaser and invoice number;
5. The itemized quantities of vinous and malt liquors purchased from other licensed Arizona wholesalers during the month the tax accrued, listed by supplier and invoice number;
6. The total quantity of vinous and malt liquors purchased in Arizona during the month the tax accrued;
7. The amount of luxury tax accrued during the month; and
8. Supporting documentation for the information provided in the return.

~~A "Wholesaler's Return of Vinous and Malt Liquor Purchased" must be filed, together, with a remittance of tax due, pursuant to A.R.S. § 42-1205. The date of filing by mail is determined pursuant to A.R.S. § 1-218. Supporting schedules must accompany this return to provide the following detailed information:~~

1. ~~Schedule of all purchases made during month on which Luxury Tax was not paid prior to receipt;~~
2. ~~Schedule of all purchases on which Arizona Luxury Tax was paid prior to receipt including returns from retailers on which luxury tax was paid;~~
3. ~~Schedule of out-of-state sales and returns to vendors outside the state;~~
4. ~~Schedule of tax-free sales in Arizona.~~

R15-3-402. Tax Return Filing Requirements – Spirituous Liquor Wholesaler **W**~~holesaler's return of spirituous liquor sold~~
On or before the statutory deadline each month, each spirituous liquor wholesaler shall file a return on a form prescribed by the Department. The return shall show the following:

1. Taxpayer's name, mailing address, business address, liquor license number, and identification number;
2. The itemized quantities of spirituous liquors sold during the month the tax accrued, listed by purchaser and invoice number;
3. The itemized quantities of spirituous liquors received during the month the tax accrued, listed by supplier and invoice number;
4. The total quantity of spirituous liquors available at the beginning and at the end of the month the tax accrued;
5. The itemized quantities of tax-free sales of spirituous liquors during the month the tax accrued, listed by purchaser and invoice number;
6. The itemized quantities of out-of-state sales of spirituous liquors during the month the tax accrued, listed by purchaser and invoice number;
7. The itemized quantities of spirituous liquors sold to other licensed Arizona wholesalers during the month the tax accrued, listed by purchaser and invoice number;
8. The total quantity of spirituous liquors sold in Arizona during the month the tax accrued;
9. The amount of luxury tax accrued during the month; and
10. Supporting documentation for the information provided in the return.

~~A "Wholesaler's Return of Spirituous Liquor Sold" must be filed, together with remittance for tax due, pursuant to A.R.S. § 42-1205. The date of filing by mail is determined pursuant to A.R.S. § 1-218. Supporting schedules must accompany this return to provide the following detailed information:~~

1. ~~Schedule of spirituous liquors imported into the state;~~
2. ~~Schedule of spirituous liquors purchased from Arizona wholesale licensees;~~
3. ~~Schedule of sales of spirituous liquor to Arizona wholesale licensees;~~
4. ~~Claim for luxury tax exemption on spirituous liquor exported from the state.~~

~~**R15-3-403. Distiller's and manufacturer's report**~~ **Repealed**
~~Every distiller, brewer, winery and/or supplier or manufacturer of alcoholic beverage who sells any of such beverages to wholesalers within the state, shall at the time of making such sale, file with the Department a copy of the invoice of such sale, showing in detail the kind of liquor or beverage sold, the quantities of each, the size of the container and the weight of the con-~~

~~tents, the alcoholic content, and the name of the person, firm or corporation to whom sold.~~

R15-3-403. Tax Return Filing Requirements – Domestic Microbrewery, Domestic Farm Winery, Domestic Cider Producer, or Beer Manufacturer

On or before the statutory deadline each month, each domestic microbrewery, domestic farm winery including domestic cider producers, or beer manufacturer subject to A.R.S. § 42-3355 shall file a return on a form prescribed by the Department. The return shall show the following:

1. Taxpayer's name, mailing address, business address, liquor license number, and identification number;
2. The itemized quantities of tax-free sales during the month the tax accrued, listed by purchaser and invoice number;
3. The itemized quantities of out-of-state sales during the month the tax accrued, listed by purchaser and invoice number;
4. The itemized quantities of liquors or beer sold to other licensed Arizona wholesalers during the month the tax accrued, listed by purchaser and invoice number;
5. The total quantity of liquors or beer sold in Arizona during the month the tax accrued;
6. The amount of luxury tax accrued during the month; and
7. Supporting documentation for the information provided in the return.

R15-3-404. ~~Wholesaler's claims for credit or refunds on unsaleable liquor~~ Repealed

~~All claims by wholesalers for credits or refunds against the Department on unsaleable liquor damaged through breakage, spoilage or turning stale by climatic conditions within the state shall be submitted in writing on the prescribed forms or other acceptable forms describing all particulars together with computations. The basis for claims or credits, exemptions or refunds for luxuries is as follows:~~

1. ~~Exports and shipments from the state of Arizona shall be verified by copy of invoice, bill of lading or acknowledgment from a department of the state to which shipped responsible for acknowledging receipt of such exports.~~
2. ~~Unsaleable malt liquors and vinous liquors spoiled at the time received and returned by wholesaler or destroyed when instructed by brewery, firm or winery; a credit memorandum from brewery, firm or winery and instructions to destroy, and an inspection by an agent of the Department prior to returning or destruction.~~
3. ~~Spirituous liquors damaged by fire or smoke or unsaleable due to short fills, improper or damaged labels.~~

R15-3-405. ~~Powdered distilled spirits~~ Repealed

~~**A.** The Luxury Tax Law and Regulations apply with respect to any alcoholic mixture or preparation in the same manner and to the same extent as with respect to other distilled spirits. The tax will be paid at the same rate per gallon, or metric equivalent, and at a proportionate rate for any quantity, as for distilled spirits of the same proof strength in liquid form.~~

~~**B.** The weight of any alcoholic mixture or preparation shall be converted to volume as follows:~~

1. ~~One pound equals .16 wine gallon.~~
2. ~~One ounce equals .01 wine gallon.~~
3. ~~One gram equals .000353 wine gallon.~~

R15-3-406. Metric Conversion ~~conversion~~

To compute the luxury tax for liquors ~~For purposes of the computation of taxes imposed upon spirituous or vinous liquors under A.R.S. § 42-1204~~ in metric containers, each taxpayer shall multiply the quantity in liters by 0.264172 to determine the equivalent quantity in gallons. ~~where such liquors are sealed in containers of metric dimensions, the following conversion table shall be used:~~

1. ~~For Spirituous Liquors:~~

	~~Bottle size~~	~~Bottles per case~~	~~U.S. gallons per case~~
~~a.~~	~~1.75 Liter~~	~~6~~	~~2.7738~~
~~b.~~	~~1.00 Liter~~	~~12~~	~~3.1701~~
~~c.~~	~~750 Milliliters~~	~~12~~	~~2.3775~~
~~d.~~	~~500 Milliliters~~	~~24~~	~~3.1701~~
~~e.~~	~~200 Milliliters~~	~~48~~	~~2.5361~~
~~f.~~	~~50 Milliliters~~	~~120~~	~~1.5850~~

2. ~~For Vinous Liquors:~~

	~~Bottle size~~	~~Bottles per case~~	~~U.S. gallons per case~~
~~a.~~	~~3.00 Liter~~	~~4~~	~~3.1701~~
~~b.~~	~~1.50 Liter~~	~~6~~	~~2.3775~~
~~c.~~	~~1.00 Liter~~	~~12~~	~~3.1701~~
~~d.~~	~~750 Milliliters~~	~~12~~	~~2.3775~~
~~e.~~	~~375 Milliliters~~	~~24~~	~~2.3775~~
~~f.~~	~~187 Milliliters~~	~~48~~	~~2.3712~~
~~g.~~	~~10 0 Milliliters~~	~~60~~	~~1.5850~~

R15-3-407. Primary Source ~~source~~ of Supply – Failure ~~failure~~ to Report ~~report~~ Sales to Arizona Wholesalers ~~by primary source~~

If ~~Upon determination by~~ the Department determines that a primary source of supply~~, as defined in A.R.S. § 4-243.01, has~~ failed to transmit ~~report~~ to the Department copies of all invoices for ~~any~~ sales ~~sale~~ of alcoholic beverages to wholesalers within the State ~~state~~ as required by A.R.S. § 4-243.01, the Department shall ~~will~~ instruct ~~notify~~ each ~~all~~ Arizona wholesaler ~~wholesalers~~ not to accept any shipment of alcoholic beverages from the ~~such~~ primary source of supply for ~~a period of~~ 1 ~~one~~ year.

R15-3-408. Arizona Wholesaler - Failure to Report Purchases from a Primary Source of Supply ~~Primary source - failure to report by Arizona wholesalers~~

If ~~Upon determination by~~ the Department determines that an Arizona wholesaler ~~has~~ failed to transmit to the Department copies of all invoices for alcoholic beverages purchased from any primary source of supply as required by A.R.S. § 4-243.01, the Department shall ~~will~~ report the ~~such~~ failure to the Department of Liquor Licenses ~~License~~ and Control.

R15-3-409. ~~Common bond~~

~~Any group or association of licensed wholesalers may furnish a common bond in such form as prescribed by the Department in the aggregate of twice the participating wholesalers monthly excise tax. Each participating wholesaler shall be shown separately as to name, location and amount. The amount of the bond shall not be less than two thousand dollars for any single wholesaler.~~

R15-3-410. Failure to File ~~make~~ a Return ~~return, failure to~~ or Pay ~~pay~~ Tax ~~tax~~

The Department shall report any failure by a licensee to file a return ~~returns~~ or pay the tax due~~,~~ to the Department of Liquor Licenses ~~License~~ and Control and the Department shall ~~may~~ request that the Department of Liquor Licenses ~~License~~ and Control ~~to~~ issue a citation against the licensee.

NOTICE OF FINAL RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 1. DEPARTMENT OF ENVIRONMENTAL QUALITY ADMINISTRATION

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R18-1-202	Repeal
R18-1-202	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific).

Authorizing statute: A.R.S. §§ 41-1003, 49-104(B)(4)

Implementing statute: A.R.S. §§ 41-1074 through 41-1076, and §§ 41-1092 through 41-1092.12

3. The effective date of the rules:

September 22, 1999

4. A list of all previous notices appearing in the Register addressing the final rules:

Notice of Proposed Rulemaking: 3 A.A.R. 2363, August 29, 1997.
Notice of Public Information: 3 A.A.R. 3313, November 21, 1997.
Notice of Docket Opening: 5 A.A.R. 1925, June 11, 1999.
Notice of Supplemental Proposed Rulemaking: 5 A.A.R. 1979, June 18, 1999.

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Martha L. Seaman

Address: Arizona Department of Environmental Quality
Rule Development Section, M0836A-829
3033 North Central Avenue
Phoenix, Arizona 85012

Telephone: (602) 207-2222 or toll-free within Arizona: (800) 234-5677, Ext. 2222

Fax: (602) 207-2251

6. An explanation of the rule, including the agency's reasons for initiating the rule:

Overview

This rulemaking addresses 1 element of the rulemaking found at R18-1-201 and 203-219 ("administrative appeals 1" which was approved by the Governor's Regulatory Review Council (GRRC) on July 13, 1999. The explanation of that rule and the summary of the economic, small business and consumer impact addressed all aspects of that rulemaking, including this element. The Department repeats the core of its earlier analysis to assist readers in understanding the current rulemaking ("administrative appeals 2") in context.

Purpose of "Administrative Appeals 1" as originally proposed

The purpose of the entire rulemaking for "administrative appeals 1" as originally proposed, is to conform the Department's rules governing administrative appeals to A.R.S. §§ 41-1092 through 41-1092.12. Those statutory provisions, which control the administrative appeal of agency actions, supersede the Department's current rules at R18-1-201 through R18-1-219.

As originally proposed, the rulemaking repeals R18-1-201 through R18-1-219 and adds new sections R18-1-201 through R18-1-207 to clarify the responsibilities of the Department under A.R.S. §§ 41-1092 through 41-1092.12. Although the Office of Administrative Hearings ("OAH") currently is responsible for conducting most appeal hearings on actions of the Department pursuant to A.R.S. §§ 41-1092 through 41-1092.12, and has recently made rules governing its conduct of those hearings (filed with the Secretary of State and effective on February 3, 1999), the Department remains responsible for processing notices of administrative appeal or requests for hearing sent to the Department, holding informal settlement conferences on administrative appeals, reviewing decisions arrived at through formal adjudication of administrative appeals before the OAH, or entertaining motions for rehearing on decisions arrived at through formal adjudication. As originally proposed, new sections R18-1-201 through R18-1-207 govern when and how the Department shall perform these tasks.

Comment received on R18-1-202 as originally proposed

ADEQ received a comment addressing R18-1-202 as originally proposed that it is not appropriate for the Department to use rulemaking to identify departmental actions that are not adjudicative and to use the rules as a basis for not processing certain notices of appeal through the OAH.

Explanation of R18-1-202 as originally proposed.

As originally proposed, R18-1-202 provided that the Department shall not schedule an administrative appeal before the OAH or a hearing before the Department, hold an informal settlement conference on an administrative appeal, review a decision arrived at through formal adjudication of the administrative appeal, entertain a motion for a rehearing on a decision arrived at through formal adjudication of the administrative appeal, or otherwise process a notice of administrative appeal or request for hearing if the notice of appeal or request for hearing concerns an agency decision or action that does not constitute a contested case or appealable agency action, because it does not determine the legal rights, duties, or privileges of the party filing the notice of appeal or request for hearing, see A.R.S. §§ 41-1001(4) and 41-1092(3), unless the notice of appeal or request for hearing is made in accordance with A.R.S. § 41-1092.12.

Under A.R.S. § 41-1092.12, the Department must process a notice of administrative appeal through the OAH even though the agency decision or action being appealed does not fall within the definition of "contested case" or "appealable agency action," if certain conditions exist: (1) the notice of appeal is filed on or after August 21, 1998 which is the effective date of Laws 1998, Chapter 85; (2) the appeal concerns an agency decision, investigation, inspection, or entry of private property; (3) the party filing the appeal has already expended reasonable attorney or professional fees regarding the decision or action being appealed; (4) the decision or action being appealed is not an order, rulemaking activity or policy making activity; (5) the decision or action is not already administratively appealable as a contested case or appealable agency action; (6) the decision or action is not already judicially appealable; (7) the party filing the appeal alleges the decision or action being appealed is arbitrary, capricious, or not in accordance with the law; (8) the party files the appeal within 10 days after the agency decision or action in question in accordance with the service provisions of A.R.S. § 41-1092.04; and (9) the Department does not cease the decision or action being appealed within 10 days after receiving the notice of appeal. If all these conditions are satisfied, then the Department must schedule a hearing with the OAH, hold an informal settlement conference, review a decision arrived at through formal adjudication, and entertain a motion for a rehearing on a decision arrived at through formal adjudication even though the decision or action being appealed does not determine legal rights, duties, or privileges. If the conditions for filing an administrative appeal under A.R.S. § 41-1092.12 are not satisfied, the rule then sets forth steps the Department must follow.

Under R18-1-202 as originally proposed, the Department may not process an administrative appeal of 4 identified types of departmental actions, because such actions do not constitute contested cases or appealable agency actions, unless the notice of appeal is filed in accordance with A.R.S. § 41-1092.12.

ADEQ has reconsidered its position with regard to R18-1-202.

ADEQ analyzed at length the comment which held that it is not appropriate for the Department to use rulemaking to identify departmental actions that are not adjudicative. That analysis, which took the position that the rulemaking did not re-define the term "appealable agency action," is contained in the rulemaking documents related to the original rulemaking.

After reconsideration, the Department has changed its position with respect to this issue. In the interest of allowing the majority of the original rulemaking to become effective in a timely manner, ADEQ withdrew R18-1-202 from the larger rulemaking and allowed the remainder of the package to proceed. This notice of final rulemaking reflects this change in R18-1-202 as described below.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable.

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

Not applicable.

9. The economic, small business, and consumer impact:

To the extent ADEQ addressed the economic impact cost savings with regard to the rule as originally proposed by not forwarding these appeals into the OAH system, these cost savings will not be realized under the changed rule. Under the changed rule, ADEQ will forward all appeals to OAH.

a. Identification of persons who will be directly affected by, bear the costs of, or directly benefit from the rule making:

This rulemaking impacts the potential administrative appellant, the Department, the Office of Administrative Hearings (OAH), and the Attorney General's Office (AGO). The potential administrative appellant may be a political subdivision, a business, or a natural person.

b. Cost-benefit analysis:

(1) The probable costs and benefits to the Department -- there will be no savings as previously anticipated associated with reducing the number of noncognizable cases that require agency head review of OAH recommended decisions.

(2) The probable costs and benefits to the OAH -- The rulemaking does impose costs on the OAH. The rulemaking would result in all appealable agency actions being forwarded to OAH.

(3) The probable costs and benefits to the Attorney General's Office -- The rulemaking does not impose costs on the AGO. The AGO would represent the Department in appeals forwarded to OAH.

(4) The probable costs and benefits to the potential administrative appellant -- The potential administrative appellant may be a political subdivision, a business, or a natural person.

The rulemaking does not impose costs on the potential administrative appellant. There is no appreciable change to an appellant whose action is determined to be noncognizable. The difference between the rule as proposed and this version is that now OAH, not ADEQ makes this determination.

c. General description of the probable impact on private and public employment:

The probable impact on private and public employment is expected to be negligible.

d. Statement of the probable impact on small businesses and consumers:

The probable impact on small businesses is expected to be negligible.

e. Statement of the probable effect on state revenues:

The probable effect on state revenues is expected to be negligible.

f. Description of less intrusive and less costly alternatives, if any:

The Department is not aware of any less intrusive or less costly alternatives.

10. A description of the changes between the proposed rule, including supplemental notices and final rules (if applicable):

R18-1-202. Notice of Appeal

~~A.~~When the Department determines that an agency action ~~rises to the level of~~ is an appealable agency action, the Department shall serve notice as ~~set forth~~ prescribed in A.R.S. § 41-1092.03(A). ~~B. The~~ Any failure of the Department to serve notice of an appealable agency action under A.R.S. § 41-1092.03(A) ~~shall~~ does not prevent a party from requesting a hearing under § 41-1092.03(B) if the request is made within 30 days of ~~receiving~~ the date on the Departmental notice of the action giving rise to the request. ~~C.~~ The Department shall forward all hearing requests made under A.R.S. § 41-1092.03 to the Office of Administrative Hearings.

11. A summary of the principal comments and the agency response to them:

There were no comments received on this rule. Changes for clarity, conciseness, and understanding have been made at the request of the Governor's Regulatory Review Council as described below.

R18-1-202. Notice of Appeal

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

When the Department determines that an agency action ~~rises to the level of~~ is an appealable agency action, the Department shall serve notice as ~~set forth~~ prescribed in A.R.S. § 41-1092.03(A). Any failure of the Department to serve notice of an appealable agency action under A.R.S. § 41-1092.03(A) does not prevent a party from requesting a hearing under § 41-1092.03(B) if the request is made within 30 days of ~~receiving~~ the date on the Departmental notice of the action giving rise to the request. The Department shall forward all hearing requests made under A.R.S. § 41-1092.03 to the Office of Administrative Hearings.

ANALYSIS: ADEQ has agreed to make these changes.

RESPONSE: The rule text now reads:

When the Department determines that an agency action is an appealable agency action, the Department shall serve notice as prescribed in A.R.S. § 41-1092.03(A). Any failure of the Department to serve notice of an appealable agency action under A.R.S. § 41-1092.03(A) does not prevent a party from requesting a hearing under § 41-1092.03(B) if the request is made within 30 days of the date on the Departmental notice of the action giving rise to the request. The Department shall forward all hearing requests made under A.R.S. § 41-1092.03 to the Office of Administrative Hearings.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rule:

Not applicable

13. Incorporations by reference and their location in the rules:

Not applicable

14. Was the rule previously adopted as an emergency rule?

No.

15. The full text of the rules follows:

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 1. DEPARTMENT OF ENVIRONMENTAL QUALITY ADMINISTRATION

ARTICLE 2. ADMINISTRATIVE APPEALS

Section

~~R18-1-202. Initiation of proceedings and notice~~ Repealed

R18-1-202. Notice of Appeal

ARTICLE 2. ADMINISTRATIVE APPEALS

~~**R18-1-202. Initiation of proceedings and notice**~~ **Repealed**

~~**A.** A contested case may be initiated only by the Department or by a person whose legal rights, duties, or privileges are required by Title 49 of the Arizona Revised Statutes; by Title 41, Chapter 6, Article 6 of the Arizona Revised Statutes; or by rule, to be determined after an opportunity for a hearing.~~

~~**B.** A contested case shall be initiated in the manner provided by the statute or rule authorizing the hearing.~~

~~1. When a contested case hearing is initiated by a request for hearing served upon the Department, the request for hearing shall specifically cite:~~

~~a. The specific actions of the Department which are the basis of the hearing request.~~

~~b. The statute or rule requiring the Department to grant that person a hearing.~~

~~2. Whenever a contested case hearing is initiated by the Department, a copy of the notice of proceedings shall be served by the Director on the parties named therein. The notice shall be in accordance with the provisions of A.R.S. § 41-1061(B). The notice shall be signed by the Director.~~

R18-1-202. Notice of Appeal

When the Department determines that an agency action is an appealable agency action, the Department shall serve notice as prescribed in A.R.S. § 41-1092.03(A). Any failure of the Department to serve notice of an appealable agency action under A.R.S. § 41-1092.03(A) does not prevent a party from requesting a hearing under § 41-1092.03(B) if the request is made within 30 days of the date on the Departmental notice of the action giving rise to the request. The Department shall forward all hearing requests made under A.R.S. § 41-1092.03 to the Office of Administrative Hearings.

NOTICE OF FINAL RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY
SOLID WASTE MANAGEMENT

PREAMBLE

1. Sections Affected — **Rulemaking Action**

Article 14	New Article
R18-13-1401	New Section
R18-13-1402	New Section
R18-13-1403	New Section
R18-13-1404	New Section
R18-13-1405	New Section
R18-13-1406	New Section
R18-13-1407	New Section
R18-13-1408	New Section
R18-13-1409	New Section
R18-13-1410	New Section
R18-13-1411	New Section
R18-13-1412	New Section
R18-13-1413	New Section
R18-13-1414	New Section
R18-13-1415	New Section
R18-13-1416	New Section
R18-13-1417	New Section
R18-13-1418	New Section
R18-13-1419	New Section
R18-13-1420	New Section

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 41-1003, 49-104.

Implementing statutes: A.R.S. §§ 49-701(19), 49-761(D), 49-761(G), 49-762, 49-762.03, 49-762.04, 49-762.06.

3. The effective date of the rules:
September 17, 1999

4. A list of all previous notices appearing in the Register addressing the final rules:
Notice of Termination: 4 A.A.R. 3791, November 13, 1998.
Notice of Docket Opening: 4 A.A.R. 3819, November 13, 1998.
Notice of Proposed Rulemaking: 4 A.A.R. 3856, November 20, 1998.

5. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name:	Martha L. Seaman
Address:	Arizona Department of Environmental Quality Rule Development Section, M0836A-829 3033 North Central Avenue Phoenix, Arizona 85012
Telephone:	(602) 207-2222 or toll-free within Arizona: (800) 234-5677, Ext. 2222
Fax:	(602) 207-2251

6. An explanation of the rule, including the agency's reasons for initiating the rule:
Pursuant to A.R.S. § 49-761, this rulemaking sets forth handling, treatment and disposal standards for biohazardous medical waste and discarded drugs.

A. Biohazardous Medical Waste Defined and Brief Summary of Regulatory Responsibility Between the Arizona Department of Environmental Quality and the Arizona Department of Health Services

The solid waste "stream" is made up of waste from various sources including household-generated solid waste, hazardous waste, special waste, sludge, biohazardous medical waste, non-biohazardous medical waste, among others. All waste in the solid waste stream is subject to regulation pursuant to Chapter 4 of Title 49, Arizona Revised Statutes. Where a source waste presents a specific risk to human health or the environment, regulations in addition to the general solid waste regulations are imposed.

Biohazardous medical waste can generally be described as medical waste from regulated generators which is either soaked with blood or which has come into contact with infectious agents capable of transmitting disease to humans. Non-biohazardous medical waste is medical waste which is neither blood-soaked nor has it come into contact with an infectious agent. An example of non-biohazardous medical waste is a paper cup or a tissue in a physician's office used in the treatment of a common cold.

A.R.S. § 49-761(D) requires that the Arizona Department of Environmental Quality (ADEQ) adopt rules regarding the regulation of biohazardous medical waste. A.R.S. § 49-761(E) permits ADEQ to decide whether to impose additional regulatory requirements (beyond the solid waste requirements) upon non-biohazardous medical waste. ADEQ believes that non-biohazardous medical waste, with the exception of discarded drugs, does not pose a risk significantly different to that of general solid waste and is adequately regulated under the existing solid waste regulations.

Based on these conclusions, the final rule sets forth handling and treatment standards for biohazardous medical waste, and addresses the proper disposal of 1 category of non-biohazardous medical waste, discarded drugs.

At the present time, ADEQ regulates medical waste as solid waste and the Arizona Department of Health Services (ADHS) governs medical waste through its regulation of hospital environmental services. When the final rules become effective, ADEQ will govern biohazardous medical waste as a special category of solid waste. The state Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Rule does not govern waste, although it regulates blood and blood products. There is some overlap of subject matter with the Bloodborne Pathogen Rule because ADEQ's final rule regulates blood and body fluids when they are discarded. For a summary of Arizona medical waste regulation, please see the proposed rule at 4 A.A.C. 3856, November 20, 1998.

In 1992, when ADEQ first began drafting biohazardous medical waste rules, about half of the states had some type of regulation. The US Environmental Protection Agency Medical Waste Tracking Act expired in 1990. Nine years later, about 44 states have medical waste rules of varying stringency while the United States Environmental Protection Agency (USEPA) has not promulgated any further regulations. Regulation at the federal level is limited to the OSHA's Bloodborne Pathogens Regulations and US Department of Transportation's Hazardous Materials Transportation Rules. The Center for Disease Control (CDC) has recommendations on the handling of hospital medical waste, and on the handling of waste from microbiological biomedical laboratories.

B. Overview of the Rules

This rule will affect persons who generate, transport, treat, or dispose in a landfill, regulated medical waste. Household generators of regulated medical waste are exempt.

The types of medical waste that will be regulated are biohazardous medical waste and discarded drugs. Biohazardous medical waste is defined as cultures and stocks, waste human blood and blood products, pathological wastes, medical sharps, and research animal waste.

All biohazardous medical waste must be treated to a high level of disinfection (which is less than sterilization) or landfilled in a segregated portion of an ADEQ approved landfill. Some additional processing, packaging, or treatment will be required for certain types of waste. For example, medical sharps must be rendered incapable of puncturing; chemotherapy waste must be incinerated or landfilled; and human body parts must be made unrecognizable. Discarded drugs must be rendered unusable before disposal.

The medical waste rules will only apply to biohazardous medical waste once it is placed out for collection and will not apply to the manner in which a generator collects, handles, and stores the waste inside the generator's place of business. Biohazardous medical waste may be treated on-site by the generator; shipped to an ADEQ approved treatment facility and treated or sent to an ADEQ approved landfill.

Treatment can be accomplished by incineration, autoclaving, or any alternative treatment technology that complies with ADEQ treatment standards. Providers of alternative treatment technologies are required to register with ADEQ. The registration process will require laboratory proof that the technology complies with ADEQ standards.

The same treatment standards apply to both the off-site and on-site treaters. If biohazardous medical waste is treated on-site, a generator must label the treated medical waste (identifying it as treated) prior to placing it out for collection by a municipal solid waste collector. Medical sharps must be encapsulated or otherwise rendered incapable of creating a stick hazard before disposal in the municipal solid waste stream.

If biohazardous medical waste is shipped off-site to either a treatment facility or a landfill, the generator must properly package the waste prior to placing it out for collection. Proper packaging is a red plastic bag placed in either a reusable container or a disposal rigid container, such as a cardboard box. Medical sharps must be placed in a rigid container to prevent puncture, then placed inside a reusable container or a disposable container. A generator may also use a mail back system for medical waste sharps. The biohazardous medical waste must always be segregated from other solid waste and can only be taken to an ADEQ approved treatment or disposal facility.

A medical waste hauler is required to be registered with ADEQ. Each hauler must provide the generator with a written receipt (tracking form) showing the amount of waste that has been accepted from the generator. This written receipt accompanies the waste until the waste is delivered to its final destination.

After treatment, the treated medical waste may be taken to a municipal solid waste landfill for disposal.

Municipal solid waste landfills that accept untreated biohazardous medical waste must follow specific operating criteria, such as a separated disposal area, and covering the medical waste with soil prior to compacting the waste.

C. Brief History of the Rulemaking

The rule was originally proposed in June of 1993. This proposed rule was withdrawn during a Governor's Regulatory Review Council hearing because of the following: differences of opinion arising from differing scientific opinions of the degree of risk posed by biohazardous medical waste; stakeholder opposition to the requirement that landfills accept untreated biohazardous medical waste from small quantity generators; and stakeholder concerns that the treatment standards were too strict and that the definition of biohazardous medical waste was too broad. ADEQ subsequently held a series of 3 facilitated medical waste roundtables with affected stakeholders.

The rule was re-proposed in May of 1996. Among other revisions, this proposed rule eliminated the small quantity generator exemption; eliminated the requirement for landfills to accept untreated waste from small quantity generators; and contained a revised definition of biohazardous medical waste. Like the 1st proposal, the rule exempted all home generated medical waste. Among comments received at the oral hearings for this proposal included the need to regulate home generated medical waste; the need to sterilize cultures and stocks; and the need to label biohazardous waste treated on-site. ADEQ responded to these comments and revised the rule to accommodate these changes. Certain of these changes constituted A "substantial change" to the rule and necessitated a supplemental proposed rulemaking, involving re-noticing the rule and another comment period.

The supplemental proposed rulemaking was proposed in November of 1996. In addition to subjecting the home health care industry to regulation, this proposed rule also required that cultures and stocks be sterilized; required

waste treated on-site be labeled; made certain limitations on the discharge of biohazardous medical waste down a sanitary sewer; required labeling of biohazardous waste treated on-site; and required registration of alternative medical waste technologies. Comments received during the comment period included opposition to regulating home health care providers; opposition to the sterilization of cultures and stocks; and opposition to the general standard of high level disinfection as regulatory overkill.

The rule was again proposed in November of 1998. Prior to this proposal, ADEQ held another roundtable discussion with affected stakeholders. In the summer of 1998, ADEQ received a petition from residents of Mohave County regarding the requirement that all biohazardous medical waste must be treated prior to placing in landfills. The petition stated that the requirement creates undue hardships for remote locations because: 1.) Transportation costs to the nearest treatment facility are very costly due to long distances; 2.) A lack of competition for hauling and disposal of biohazardous medical waste creates excessive costs and interferes with efficient business management; and 3.) Missed service calls cause biohazardous medical waste to be held until the next scheduled collection day which is sometimes more than the maximum 7 days allowed in rule without costly refrigeration. ADEQ responded to this petition by proposing a rule which allows municipal solid waste landfills to decide whether or not to accept untreated biohazardous medical waste and if accepted, specific operating criteria are to be followed. Comments received at the oral hearings for this rule included: differences of opinion arising from differing scientific opinions of the degree of risk posed by biohazardous medical waste; opposition to the general standard of high level disinfection; opposition to the sterilization requirement for cultures and stocks; a request for clarification of the home health care exemption; and a questioning of the cost versus benefits of the rule. These comments were considered in revising the final rule.

D. The Final Rule and ADEQ's Rationale

Risk. There is no consensus nationwide about the degree of risk posed to public health or the environment by biohazardous medical waste. It has been recognized, however, that biohazardous medical waste does present an occupational hazard to workers such as janitors, waste handlers, landfill workers and others who come into contact with medical sharps and untreated biohazardous medical waste in the solid waste stream. Whether untreated biohazardous medical waste presents a hazard to the general public depends upon the specific circumstances involved. It has been demonstrated that, if there is less than adequate oversight, biohazardous medical waste ends up in campgrounds, roadways, in the desert and other areas where an unsuspecting public may make contact with it.

In many respects, the risk posed by untreated biohazardous medical waste is similar to the risk posed by the airline industry -- low risk, but high impact. The relatively low probability of an airline crash does not mean that the airline industry should remain unregulated given the high consequence of even a single disaster. Likewise, for health care workers who have had needle stick injuries and contract Hepatitis B Virus (HBV) the impact is potentially very high: chronic liver disease and death.

Simplified rule. When ADEQ began drafting these rules, the regulated community urged that they be kept as simple and "user friendly" as possible. One commenter suggested that any person handling the waste should be able to look at it and know if it is biohazardous without waiting for laboratory results or needing a college degree in biochemistry. In response to this desire for simplicity, ADEQ classified medical waste into 1 groups, biohazardous medical waste and discarded drugs. The biohazardous medical waste group is composed of cultures and stocks, waste human blood and blood products, pathological wastes, medical sharps, and research animal waste. Therefore, anyone can recognize waste from 1 of these subgroups and know it is regulated medical waste and must be handled as such. Consistent with this approach, ADEQ has generally avoided the approach of singling out certain wastes for special handling. For instance, ADEQ has declined to single out in human pathologic wastes prion-related diseases (such as Kuru and Creutzfeldt-Jakob Disease) for identification and incineration and instead has required the class of wastes to be treated to a high disinfection level.

Do not over regulate. Another commenter urged ADEQ not to over regulate. ADEQ has responded to this suggestion by its approach to generally base the rule on the medical community's existing medical waste management practices. Briefly, these practices can be summarized as either treating the waste on-site and then disposing of the treated medical waste in the municipal solid waste stream; or packaging the biohazardous medical waste and shipping it off-site for treatment or placement in a landfill. "On-site" means the site of waste generation and "off-site" means all other locations. ADEQ has found that the most common treatment methods being used are autoclaving and incineration. Accordingly, these rules allow for both on-site and off-site treatment of the biohazardous medical waste by autoclaving and incineration. In addition, the rules allow for any alternative treatment technology that can meet the treatment standards established in the rule, high level disinfection. This treatment standard is a step down from sterilization, which is the treatment level achieved by incineration and autoclaving. Also, the rules allow for untreated biohazardous medical waste to be taken to a landfill for disposal, if the landfill 1st obtains ADEQ facility plan approval and follows certain handling requirements. This was a common practice until the late 1980s, prior to the emergence of commercial off-site treatment facilities.

7. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where he public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

The Department has utilized the following studies in this rulemaking: "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" (Treatment Manual), prepared by the State and Territorial Association on Alternate Treatment Technologies (April, 1994); "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" (Treatment Manual), prepared by the State and Territorial Association on Alternate Treatment Technologies (Revised, December, 1998); "Biosafety in Microbiological and Biomedical Laboratories" (U.S. Department of Health and Human Services, Center for Disease Control, 3rd Edition); "Arizona Department of Environmental Quality 1995 Generator Study"; U.S. Department of Commerce, Bureau of the Census, County Business Patterns 1989 and 1992 Arizona; Arizona State Veterinary Medical Examining Board (computer printout dated 2/23/95); Arizona Department of Health Services, Office of Lab Licensure and Certification (Oscar Report 86 dated 5/11/95); Arizona State Board of Dental Examiners (copy of labels, no date); Arizona State Board of Funeral Directors and Embalmers (crematory list dated 2/03/95 and establishment list, date printed 2/23/95); Arizona Hospital and Healthcare Association (labels, no date); Arizona Medical Association (purchased labels from a computer generated random sample); Arizona Department of Health Services, Health and Child Care Review Services, Health Care Licensure, Medical Facilities Section (Medicare certified/state licensed outpatient treatment clinics dated 6/02/95, Medicare certified/state licensed ambulatory surgical centers and state licensed outpatient surgical centers dated 3/01/93, Medicare certified comprehensive outpatient rehabilitation facilities dated 3/04/94, state licensed infirmaries dated 6/02/94, Medicare certified/state licensed rural health clinics dated 6/02/95, state licensed recovery care centers dated 2/01/94, licensed residential care institutions dated 6/02/95, Medicare certified/state licensed nursing care institutions dated 5/04/93, licensed adult day health care facilities dated 4/03/95, licensed supervisory care homes dated 5/04/93, licensed adult care homes dated 6/02/95, licensed respite unclassified facilities dated 4/03/95, and state licensed unclassified health care institutions dated 11/01/94). These materials are available for review at ADEQ at 3033 North Central Avenue, Phoenix, Arizona, 85012.

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

Not applicable.

9. The economic, small business, and consumer impact:

A. Prologue

1. Rule Identification and Classes of Waste Regulated

The rulemaking will be codified in 18 A.A.C. Chapter 13, in a new Article 14 (Biohazardous Medical Waste and Discarded Drugs), consisting of sections R18-13-1401 through R18-13-1420.

This rulemaking regulates 5 classes of biohazardous medical waste (cultures and stocks, waste human blood and blood products, pathological wastes, research animal waste, and medical sharps) and discarded drugs (non-biohazardous). It also requires that chemotherapy waste either be incinerated or disposed in either an approved solid waste landfill or a hazardous waste landfill. Specific rule provisions prescribe packaging, storing, transporting, and treating/disposal standards for these wastes. Overall, these rule provisions may be viewed as minimum standards that generally are being practiced by the healthcare industry in Arizona.

For additional information, see the preliminary economic, small business, and consumer impact statement, referred to as the *1996 EIS*. It was prepared for the prior rulemaking, and it is available from ADEQ in the Medical Waste docket file. It contains tables, figures, appendices, endnotes, references, and more details about the mid-1995 generator survey referred to in this discussion.

2. General Conclusions

Regulatory standards for medical waste vary across states. Despite this fact, common management requirements do exist in many of the states. They may include such elements as type of entity regulated, treatment standards, various handling procedures, and management of medical sharps as a separate waste stream. The overall goal is to properly manage biohazardous medical waste to reduce the risk of exposure to healthcare workers, occupational subgroups, and the general public. It has been suggested that any practices that elevate risks to human health and the environment should be eliminated through regulatory requirements.[1]

Essentially, this rulemaking codifies current industry standards and practices. For example, it is a common practice for hospitals and numerous other generators to contract with off-site treaters to pick up their biohazardous medical waste for treatment and disposal. Other generators treat their waste on-site. Because it codifies current behavior and ADEQ assumes generators act in their own best economic interest, this rulemaking provides flexible and cost effec-

tive options for generators. For small quantity generators, this includes relatively inexpensive options for handling medical sharps. Another option allows for the landfilling of untreated biohazardous medical waste.

ADEQ believes it reasonably balances risks posed by biohazardous medical waste with compliance costs. This principally is a result of 2 factors: (1) the impact of this rulemaking is expected to be minimal; (2) the standards for handling biohazardous medical waste probably would be judged acceptable by both the healthcare industry and the general public. The impact of this rulemaking is "minimal" because the majority of Arizona's generators currently are following acceptable industry standards for the management of biohazardous medical waste. As a result of these factors, ADEQ expects probable benefits of this rulemaking to outweigh probable costs.

Scientific literature and other evidence show that current practices and methods of treatment of medical waste have not resulted in a public health hazard. In fact, public health is unlikely to be adversely impacted by biohazardous medical waste generated in the current healthcare setting. Preventive measures have controlled a number of infectious agents that are capable of medical waste disease transmission. Thus, current practices of general hygiene, sanitation, cleaning, and either disinfecting or sterilizing medical waste represent adequate preventive procedures for controlling potential health hazards.[2]

Generators have flexibility in making treatment decisions that are economically feasible because this rulemaking does not mandate a specific treatment methodology, but instead sets forth specified treatment standards that must be met. A benefit of this approach is that alternative treatment technologies are free to enter the Arizona market. A generator may treat its waste on-site by incinerating, autoclaving (steam or other method), or using another treatment method that would meet the treatment standards. In addition, a generator of medical sharps may use a mail-back kit or an encapsulation method. A generator may contract with an off-site treater (ADEQ approved medical waste treatment facility). Finally, a generator may dispose of untreated biohazardous medical waste in a landfill whose owner/operator has agreed to accept this waste stream and the landfill has received ADEQ plan approval. Therefore, a generator may choose among 3 treatment/disposal options: (1) treat on-site, (2) treat off-site, or (3) landfill untreated waste.

In addition to expected health and welfare benefits, ADEQ anticipates benefits to accrue from regulatory certainty and enforcement actions. A major part of anticipated benefits are derived from preventive measures in the management of biohazardous medical waste. It also is possible for certain occupational subgroups outside the healthcare setting (refuse workers and landfill personnel, such as waste handlers, collectors, and equipment maintenance workers) to derive potential benefits from reduced workplace injuries.[3] Medical sharps are dangerous even if they are not contaminated. If contaminated, however, pathogenic microorganisms could be transmitted to the worker through accidental needle sticks. Theoretically, the risk is not just limited to medical sharps because other biohazardous medial waste could carry pathogens in blood or certain other body fluids. In addition to workers at risk, their family members, subsequently, could be placed at risk if workers become infected. Thus, if the potential for workplace injuries is reduced, it is logical that certain costs could be avoided in terms of treatment costs, absenteeism (work days lost), and other costs associated with morbidity and mortality.[4]

3. Lack of Unanimity

Medical waste caused tremendous concern for the public and politicians from a health and safety perspective during the late 1980s and early 1990s (see Appendix A). It has been suggested that much of this concern was "fueled by the acquired immune deficiency syndrome (AIDS) epidemic." The remaining concern may have been over environmental and aesthetic issues, coupled with the fact that in the late 1980s the disposal of medical sharps was not comprehensively regulated by federal, state, or local governments.[5] Together, these concerns were dramatized by the news media. It also has been stated that media coverage, very often, has been intense and misleading.[6] The result has been public outrage over the alleged mismanagement of medical waste and a variety of regulatory responses by different states.

Contrary to what the general public may have believed a decade ago, outside the healthcare setting, the likelihood for hepatitis B virus (HBV) or human immunodeficiency virus (HIV) infections occurring to the public due to a medical waste related injury is not very high.[7] According to Centers for Disease Control, the acquired immune deficiency syndrome (AIDS) virus is fragile and dies quickly when exposed to the environment. However, HBV can survive in dried blood for several weeks; hence, the potential for HBV infection following contact with medical waste is likely much higher than that associated with HIV.[8] The general conclusion is that inappropriately managed medical sharps could increase the opportunity for injury and infection for certain occupational subgroups outside the healthcare setting.[9]

There is a perspective that medical waste may represent only a minimal hazard in terms of its infective risk. This is based on the premise that household waste may be as infectious as most untreated biohazardous medical waste

(household waste may contain 100 times, or greater, more microorganisms with pathogenic potential for humans compared to medical waste) and no epidemiologic evidence exists that the management of biohazardous medical waste from hospitals has caused disease in the community. Those with this perspective conclude that regulators have imposed "costly standards" on the healthcare industry without real scientific justification.[10]

At the other end of the risk spectrum, is the view that biohazardous medical waste does represent a potential for injury and infection, but preventive measures have controlled a number of infectious agents that are capable of medical waste disease transmission. While most biohazardous medical waste may represent a minimal infective risk, not all biohazardous medical waste should be considered risk free, especially medical sharps. The risk is that a biological agent or infectious material may cause infection, disease, or death. In addition, the risk for injury and infection is greater for certain occupational subgroups than the public at large. And these subgroups include professional staff and workers both inside and outside of the healthcare setting.

According to this viewpoint, biohazardous medical waste should be managed to avoid exposing humans to it. Exposure can be reduced by taking precautions regarding how biohazardous medical waste is handled, packaged, and treated. In addition, appropriate safety precautions and personal hygiene practices should be followed. The effect of these measures should result in reduced risks. Sharps, for example, can cut, puncture, and lacerate with or without the transmission of infection. Thus, if certain methods of management are used, the outcome should be reduced injuries and increased protection from disease transmission. Stated in another way, human exposure probably cannot be eliminated, but it can be reduced by reducing the modes of transmission between people and infectious agents or materials in this waste stream (inside and outside the healthcare setting).

Assessing public health risks is a very difficult task; the literature cites conflicting opinions and mainly focuses on hospital waste. [11] Because of the uncertainty about the risks associated with managing biohazardous medical waste, it is important to include a few statements about risk management and risk analysis. Risk management is the process of evaluating and choosing options to implement and enforce. It normally includes a margin of safety which provides assurances that would reduce risks (injury, infection, illness, disease, and death). On the other hand, risk analysis is simply the science of measuring the probability and magnitude of harm (calculated risk). Although regulatory agencies are concerned with actual risk, it rarely can be measured. Therefore, regulatory standards seek to capture the calculated risk, but which may be overstated through regulatory policy and perceived risk.[12] Thus, uncertainty about the actual risk of biohazardous medical waste has polarized the risk spectrum. This explains, in part, differences of opinion about how this waste stream should be managed in Arizona.

ADEQ acknowledges there is no consensus about the degree of risk biohazardous medical waste poses, the potential for exposure, the level of microbial inactivation required for treatment, or whether untreated biohazardous medical waste should be landfilled. ADEQ also realizes the debate over the potential risks posed by biohazardous medical waste cannot be resolved at this time. But the lack of unanimity about how biohazardous medical waste is best managed does not mean that certain standards and precautions should not be implemented by rule. Likewise, even though benefits cannot be quantified, it does not mean that probable benefits cannot outweigh probable costs.

Although there is an opinion that public health risks of biohazardous medical waste generated by households are equivalent to those relating to "regulated" medical waste, subtle differences often are not discussed. For example, biohazardous medical waste generated by the healthcare industry, and especially hospitals which produce about 2/3 of the total biohazardous medical waste, may be viewed as a more concentrated source by volume at any 1 location as compared to the ubiquitous household infectious waste. Another difference is that biohazardous medical waste generated from the healthcare setting tends to contain more blood and blood components than residential waste.[13] In addition, hospital waste may show a wider range of bacteria.[14] Finally, because of the variety of generators, some waste potentially may be more infectious than others, such as laboratory waste.

B. Overview of Impacts

1. Treatment Costs: Past Survey Results

Based on inferences from ADEQ's mid-1995 generator survey, as many as 95% of Arizona's estimated 7,300 generators, essentially, could be handling and treating their biohazardous medical waste in accordance with standards set forth in this rulemaking.[15] This treatment rate includes generators transferring their waste to another division or generator, presumably for treatment. If this inference is correct, 5% would be considered out of compliance. The proposed EIS estimated an overall compliance cost to these generators for the proper treating/disposing of their biohazardous medical waste to be $350,000 annually (see *EIS 1996*).[16] Several factors may have acted together to result in such a high compliance rate regarding treatment of biohazardous medical waste (see Appendix B).

Paraphrasing views expressed by some generators is that ADEQ should not view the anticipated compliance costs for generators to treat their biohazardous medical waste as minimal. Consequently, off-site treaters will benefit handsomely as a result of this rulemaking with benefits lagging costs. Contrary to these opinions, ADEQ believes this will not be the case. Stakeholders making these claims have not provided any evidence of support. Furthermore, based on inferences from the mid-1995 generator survey and current industry practices, the impact of the estimated 5% of generators currently not treating (or adequately) treating their biohazardous medical waste suggests a minimal economic impact.

To put the estimated compliance in perspective, one can calculate an annualized cost for all categories of generators to have their biohazardous medical waste treated off-site and compare that cost to the estimated annual cost of $350,000 for the 5% of generators currently not treating. The result of the comparison reveals that the estimated compliance cost to these generators, who would now have to begin treating their biohazardous medical waste, represents less than 3% of the total cost to the industry as a whole (if all contracted for off-site treatment). In view of the baseline selected for this rulemaking, from which impacts are assessed, not all compliance costs would be considered incremental (see Appendix C). This means that the actual impact could be less than $350,000.

Generators have several options for managing their biohazardous medical waste: (1) treat on-site, (2) treat off-site, or (3) dispose untreated biohazardous medical waste in a landfill. An unknown proportion of generators, most of which probably would be small quantity generators, may decide not to contract with an off-site treater. Other generators that currently contract with an off-site treater may switch to an on-site treatment method, or use mail-back kits or an encapsulation method for disposing of medical sharps (refer to C.1.). Thus, if part of the 5% of generators currently not treating choose not to contract with off-site treaters and use other options, this would tend to lower the overall compliance costs. Industry wide, these costs also could be lowered if the proportion of generators treating their waste has increased in the state since mid-1995.

ADEQ expects compliance costs for individual generators to vary according to 4 conditions: (1) amount of biohazardous medical waste generated; (2) geographic location; (3) type of treatment option chosen; and (4) costs for complying with other handling requirements. In broad terms, the greater the quantity of waste, the greater the potential is for a generator to gain a lower cost per pound. For example, hospitals have been able to negotiate off-site treatment costs around $0.20 per pound ($400 per ton weighted average) compared to dentists' offices, which generate the least amount of waste, that pay an average of $5.88 per pound ($11,760 per ton weighted average). Likewise, other large quantity generators have been able to negotiate lower prices, but perhaps to a lesser degree (refer to Table 1).[17]

Because most off-site treaters charge generators by the container, an equivalent cost per pound is dependent upon a variety of factors, including the off-site treater's pricing scheme. These other factors include: number of containers picked up, volume of the containers, volume of waste placed into the containers, pick up schedule, and distance from the treater's facility in cases where a transportation surcharge is assessed by the off-site treater. For example, some generators are on a pick up schedule that does not allow their containers to become full prior to being picked up. Others, may pay a $35 to $50 surcharge because of the distance from the off-site treaters' facility.

2. Other Compliance Costs

The majority of medical waste disposal costs for the healthcare industry have been incurred through voluntary choices by generators. As a result, corresponding health, welfare, and environmental benefits have been realized in this state. But there are minimal costs yet to be incurred by generators, and concomitantly, unquantifiable benefits yet to be realized.

Other compliance costs include a combination of both one-time costs and annual expenditures for meeting packaging, storing, securing and recordkeeping requirements. Together, ADEQ estimates these costs also to be minimal at less than $200,000 (refer to C.2.).

Even though comments have been made that estimated costs will exceed any benefits, ADEQ does not concur with this supposition. This statement has a foundation that no risks are posed by biohazardous medical waste either inside or outside the healthcare setting. However, this conclusion has not been supported and ADEQ has not received any data or information that would support a conclusion that no benefits would be gained from this rulemaking.

3. Classes of Persons Impacted

ADEQ expects that the entities listed below could be impacted by this rulemaking. These entities could be directly affected, that is, they could bear costs or directly benefit from this rulemaking.

> Hospital and non-hospital generators, off-site treaters (medical waste treatment facilities), medical waste transporters, persons in possession of biohazardous medical waste not meeting treatment standards, owners/operators of landfills, providers of alternative medical waste treatment technologies (manufacturers, agents,

or vendors), certain occupational subgroups outside the healthcare setting (refuse workers and landfill personnel), ADEQ, consumers of healthcare services, and general public.

Note that healthcare professionals and workers (both patient and non-patient care workers) could come into contact with biohazardous medical waste during their daily work. However, biohazardous medical waste not set out for collection would not be considered "biohazardous medical waste" regulated by this rulemaking. Additionally, the general public may come in contact with biohazardous medical waste if improperly managed by the regulated entities. The public also may encounter biohazardous medical waste through in-home health care (self-care or home healthcare providers), illegal intravenous drug use, or public scavenging in landfills or transfer stations, all of which are not regulated by this rulemaking.[18]

The universe of generators includes hospital generators (110 facilities) and non-hospital generators (7,046 facilities). Non-hospital generators comprise 6 categories: physicians' offices and clinics; dentists' offices; nursing and long-term care facilities; veterinarians; funeral homes/crematories; and laboratories.[19] These groups also include a very small proportion of political subdivisions (public generators) operating county jails, health departments, clinics, and hospitals. Based on survey findings, these public generators are expected to be impacted in the same manner as the private generators. Table 1 summarizes the findings of the generator survey.

4. Exemptions From Rule Provisions

This rulemaking excludes certain entities from the requirements of this rulemaking. For example, it does not govern biohazardous medical waste generated from self-care or healthcare providers in private, public, or semi-public residences, unless such facilities are licensed by the Arizona Department of Health Services. It also excludes the following: law enforcement personnel handling biohazardous medical waste for law enforcement purposes, persons returning unused medical sharps to the manufacturer, persons sending medical sharps to a treatment facility via mail-back kits, persons discharging discarded drugs and liquid wastes (excluding cultures and stocks) into the sanitary sewer, and persons reconditioning medical treatment devices. It also exempts human corpses, remains, and anatomical parts intended for interment or cremation. Additionally, a few entities are exempt from some of the requirements of this rulemaking. Refer to R18-13-1403.

C. Compliance Costs

1. Comments About Treatment/Disposal Costs by Class of Waste

This rulemaking establishes minimum compliance requirements for managing biohazardous medical waste. Generators can make a business decision on which of the several options for treatment and disposal would provide the most cost saving benefits or prove to be the most beneficial. Examples of treatment options for generators by class of waste are summarized below. In large part, the requirements of this rulemaking currently are being practiced by the healthcare industry.

The term "incremental impact" means probable costs and benefits that would occur as a result of this rulemaking becoming effective, compared to the costs and benefits in absence of this proposed rule. For example, past expenditures, and any future ones that would be incurred regardless of this rule, would not be considered incremental costs (see Appendix C).

Cultures and stocks

Generally, the mid-1995 generator survey did not reveal much about this class of waste. However, because of Centers for Disease Control (CDC) recommendations, this waste is handled as a separate waste stream by many, if not most, generators. The standard treatment procedure that CDC recommends is to either incinerate or autoclave. Some facilities pre-treat this class of waste prior to final treatment. It has been reported to ADEQ that a generator who responded to a recent Arizona Hospital and Healthcare Association survey sends its cultures and stocks to an off-site microwave treatment facility. However, without further information regarding the facility, ADEQ is unable to evaluate the impact of this rulemaking on this facility.

This rulemaking allows cultures and stocks to be incinerated or autoclaved, as well as to be treated to high level disinfection (level III) by alternative medical waste technology (such as microwave treatment). If treated off-site, this class of waste must be packaged in a leakproof container surrounded by an absorbent material, then placed inside of a ridged container, and placed inside a 3rd rigid container. This also is a U.S. Department of Transportation requirement. It is unknown what the impact will be to generators, but ADEQ expects the impacts to be minimal, due to the fact that transporters are complying with the federal law now in the absence of the ADEQ rule.

Medical sharps

The mid-1995 generator survey revealed that the proportion of medical sharps produced varied by the category of generator (18% for hospitals and 65% for dentists' offices). The majority of sharps are disposed in sharps containers and treated off-site. Based on the survey, the methods of disposal were: (1) place into a sharps container for either off-site or on-site treatment/disposal; (2) throw into a dumpster with other solid waste; (3) send to a treatment facility in a mail-back kit (U.S. Postal Service or private shipping agent); (4) encapsulate and dispose in solid waste stream.

Treaters have a variety of options for disposal, except placing medical sharps directly into the solid waste stream, unless they 1st have been encapsulated or rendered incapable of creating a stick hazard. ADEQ believes that some generators will be impacted, particularly small quantity generators. However, this rulemaking provides cost saving alternatives compared to contracting with off-site treaters (refer to F.2.). For example, a generator may use a mail-back kit or an encapsulation method (treatment not required), both of which have similar costs. A dentist's office, or other small quantity generator, could spend approximately one-half the average monthly cost for an off-site treater to pick up its waste ($15 to $22 vs. $36).[20] This savings could amount to even more if the generator is located in a rural area and the off-site treater charges an additional pick up fee (transportation surcharge) because of the distance from the treatment facility. A generator also may have a pick up schedule by an off-site treater that does not allow for the container to be full prior to pick up. Changing the pick up schedule or choosing another option could generate cost saving benefits for some generators. The actual cost savings will depend on the method selected by the generator.

Waste human blood and blood products

Although the mid-1995 generator survey asked respondents for a description of the types of biohazardous medical waste generated and how it is disposed (by checking categories), very few indicated blood or blood products were "discharg[ed] into a sanitary sewer system." Most respondents chose the category: "contract with medical waste hauler/treatment facility." However, a few of the various categories of generators indicated they disposed of blood and blood products into the sanitary sewer.

Typically, blood and blood products, as well as pathological and animal wastes, are disposed of by discharging them into a sanitary sewer system. This method is considered acceptable because the waste is diluted by residential sewage to well below concentrations needed for bloodborne disease transmission.[21] Other methods of disposal include placing the waste in dumpsters or containers for solid waste pickup (another survey category); treating on-site or off-site by incinerating or autoclaving or by an alternative treatment technology.

This rulemaking requires generators to either treat this class of waste (on-site or off-site) or dispose of it down the sanitary sewer. Although this rulemaking may impact some generators, ADEQ believes the impact will be insignificant.

Pathological wastes

This class of waste includes organs and body parts removed during surgery or autopsy. The mid-1995 generator survey did not provide much information about this class of waste except that it was treated on-site or off-site by either incinerating or autoclaving.

This rulemaking requires generators to treat this class of waste and render it unrecognizable. It can be treated by traditional methods or an alternative treatment technology. However, if microwaving is used, it must be pre-processed by grinding or some other procedure to break up its mass. ADEQ believes this rulemaking will have minor to no impacts on generators.

Research animal wastes

This class of waste includes carcasses and body parts of animals and discarded materials in the production of biologicals, pharmaceutical testing, or other testing in which animals are inoculated with communicable diseases. The mid-1995 generator survey provided minimal information about this class of waste. The requirements for handling this class of waste are the same as for pathological wastes in accordance with CDC recommendations (see above). Again, ADEQ believes this rulemaking will have minor to no impacts on generators.

Discarded drugs

The mid-1995 generator survey revealed that generators dispose of this class of waste by the following methods: (1) return to manufacturer, distributor, or pharmacy; (2) send to an authorized return center; (3) dispose in a biohazardous container; (4) discharge into the sanitary sewer; (5) destroy on-site with other waste; and (6) throw into a dumpster with other municipal solid waste. Although generators used a combination of methods, most generators place discarded drugs into biohazardous containers because it was convenient for them.

Generators may continue to use a variety of disposal options, except placing discarded drugs directly into the solid waste stream. This rulemaking requires generators to render the drugs unusable prior to disposal in the dumpster.

Rendering the drugs unusable could include crushing, grinding, bleaching (using hypochlorite or iodophors), or diluting prior to disposal. Some generators could be impacted by this requirement, but ADEQ expects the impact to be minimal.

2. Other Compliance Costs

Other compliance costs to entities not in compliance include a combination of both one-time costs and annual expenditures for meeting new standards for such elements as: packaging, storing, securing, reporting, labeling, manifesting, transporting, and recordkeeping requirements. Thus, various categories of generators and other entities could be affected by increased compliance costs. Examples of other costs to entities include: developing transportation management plans, registering medical waste alternative treatment technologies, amending approved facility plans, and plan reviews for landfills opting to accept untreated biohazardous medical waste. Together, ADEQ estimates these costs to be minimal, probably less than $200,000.

ADEQ expects some compliance costs to be very minimal, such as the cost for generators treating on-site to label their treated waste and the cost of registering medical waste transporters and providers of alternative medical waste treatment technologies. Some counties are requiring transporters to be permitted and this same information could be sent to ADEQ for registering these transporters.

3. Costs to ADEQ

Costs to ADEQ are expected to be very minimal. Potential costs could arise from any of the following: (1) investigating complaints; (2) registering transporters and alternative medical treatment technologies; (3) performing plan reviews; and (4) making inspections. Although performing plan reviews represents a cost to ADEQ, this cost is reimbursed by plan review fees. The current ADEQ staff is capable of handling all of these regulatory activities.

D. Expected Benefits

1. Need for Rulemaking

This rulemaking is needed to fulfill the legislative mandate of 1990. ADEQ also realizes that a variety of potential benefits, as previously noted in this EIS, could accrue to various entities. Even though there is a significant trend towards treatment, there still is a small proportion of generators who currently are not treating their biohazardous medical waste (inferred to be about 5% in 1995) or following current industry standards and practices. Without this rulemaking, there is no requirement to properly manage biohazardous medical waste once it has been set out for treatment/disposal. Without this rulemaking, ADEQ would have difficulty eliminating compliance problems with the management of biohazardous medical waste relating to storing, transporting, treating, and disposing.

2. Potential Benefits

Many of the rule provisions can be referred to as "preventive measures," designed to reduce the risk of exposure of biohazardous medical waste. If handling practices and procedures can reduce workplace injuries outside the healthcare setting, then, actual benefits would accrue. Waste handlers, for instance, are at risk to exposure of needle stick injuries (refer to A.2. above). Furthermore, if the practice could be eliminated by generators who dispose of untreated biohazardous medial waste into the solid waste stream, either by placing the waste in red bags or concealing the red bags inside of black bags, this potentially could reduce risks.

Controlling risks from human exposure to bloodborne pathogens, such as HBV, and incorporating a variety of preventive measures to reduce injury and health hazards, could result in potential benefits.[22] Although certain occupational subgroups outside the healthcare setting may have the greatest potential for benefits to accrue, other entities also may realize benefits. Therefore, primary benefits of this rulemaking that potentially could accrue include the following:

(1) further reducing risks of exposure, thereby reducing injury, illness, disease, and, perhaps, mortality (principally for refuse workers and landfill personnel) and

(2) generating reasonable safety precautions for handling biohazardous medical waste, thereby addressing the public's perceived risk of biohazardous medical waste mismanagement.

Because the concept of risk includes uncertain and undesired elements, the central question becomes: what precautions are necessary to judge the management practices of biohazardous medical waste as "safe?" Naturally, the risk, which encompasses more than a "true" risk, includes a socially determined risk. Because this rulemaking codifies practices that generally are being practiced by the healthcare industry, both the public and the healthcare industry should regard the risks as acceptable (refer to A.3.). Even so, the general public is not likely to be negatively affected by biohazardous medical waste generated in the healthcare setting. But the public could gain a benefit from improved

management of this waste stream, including from ADEQ enforcing rule provisions and eliminating violations. However, due to the current practices of generators, the potential for a negative economic impact to them should be minimal. Additionally, secondary benefits (not considered an incremental impact) could include reduced workplace injuries for occupational subgroups inside the healthcare setting (refer to A.2. above and endnote #9).

The 2 primary benefits identified above are thought to be a result of this rulemaking because it accomplishes all of the following:

(1) meets legislative mandate;
(2) provides regulatory certainty;
(3) helps ADEQ to pursue enforcement actions against violators which should reduce incidents of improper disposal;
(4) facilitates consistency on how generators treat/dispose of their biohazardous medical waste (it also ensures that generators who currently treat their waste on a voluntary basis will continue to do so, as well as to comply with other rule provisions; generators who are not presently treating their waste will begin treating, as well as to comply with other rule provisions);
(5) codifies the current "good housekeeping" practices;
(6) provides a regulatory alternative for waste disposal (landfilling of untreated biohazardous medical waste); and
(7) improves awareness that could mitigate careless behavior.

As a result of primary anticipated benefits, ADEQ expects probable benefits to outweigh probable costs. The problem is quantifying potential benefits of this rulemaking. Even if this rulemaking does not result in fewer injuries, diseases prevented, or lives saved, the potential exists for benefits to exceed costs by implementing "preventive measures" and providing "regulatory certainty."

Based on a risk spectrum (refer to A.3.), there is a difference of opinion about the risks posed by biohazardous medical waste. However, there may be a consensus that the transmission of HBV is possible, as well as other infectious diseases from bloodborne pathogens. In addition, the risk for disease transmission from cultures and stocks may be of concern. Thus, ADEQ believes the proper handling and treatment of the biohazardous medical waste stream does reduce the potential for injury and the transmission of diseases, which in turn, generates potential benefits.

E. Cost-Effective Alternatives

1. Generator Flexibility

This rulemaking does not mandate a specific treatment methodology. Instead, it sets treatment standards. In this way it allows new alternative treatment technologies to enter the Arizona market. Therefore, a generator can choose the best treatment options for its business. This would include both on-site and off-site treatment options. For some generators, an option for reducing business costs may be to segregate non-regulated medical waste from biohazardous medical waste.

For some small quantity generators, the mail-back kit, or on-site encapsulation for medical sharps, may be the most economical method. For other generators, it may mean fewer pickups by an off-site treater, or a combination of fewer pickups and purchasing larger containers. It may also mean some generators will have to construct a larger storage area or purchase a refrigeration unit. For yet other generators, it may mean purchasing an autoclave, or another comparable type of equipment for treatment. For generators that decide to purchase a bench top autoclave, the cost could range from $1,500 to $5,000.

Although it is expected that most generators will continue to have their biohazardous medical waste treated off-site, some will treat their waste on-site. Another option allowed in this rulemaking is for generators to send untreated biohazardous medical waste to a landfill for disposal. However, each landfill owner/operator who agrees to accept this waste stream must follow specified best management practices (BMPs) set forth in this rulemaking. Currently, there is no prohibition against taking untreated biohazardous medical waste to a landfill, but there are no BMPs on how a landfill must handle this waste stream. Presently, most landfills refuse to accept untreated biohazardous medical waste which may be due to the lack of medical waste rules in this state.

As a direct result of landfills following these BMPs, ADEQ expects disposal costs to increase for generators choosing this disposal method. The generators opting to dispose of untreated waste could be impacted by these costs being passed on to them, but the costs may be less than what comparable generators currently pay to have their waste transported off-site and treated. For generators located in rural areas of the state, the landfilling of untreated biohazardous medical waste may represent a significant cost saving benefit.

2. Impacts of Landfilling Option

Increased costs for landfills accepting untreated biohazardous medical waste are expected to be a result of the following requirements: (1) separating the disposal area from the general purpose area; (2) posting signs to identify the area; (3) prohibiting salvaging in the area; and (4) applying a sufficiently thick cover over the waste so that compaction equipment will not come into contact with the untreated waste. In addition, a landfill will have to amend its plan to accept untreated waste. Plan review costs for approval of an amended plan could range from a few hundred dollars to $18,500. ADEQ anticipates the average cost to review most amended plans to be less than $5,000. Although all costs incurred by landfills are expected to be passed on to generators opting for this disposal method, an approximated cost per pound is unknown at this time.

F. Small Business Impact Reduction

1. Statute Requirements

ADEQ is sensitive to the concerns of small businesses and the impact this rulemaking could have upon them. Accordingly, ADEQ has considered each of the methods prescribed in A.R.S. § 41-1035 for reducing the impact on small businesses. Likewise, it has considered each of the methods prescribed in A.R.S. § 41-1055(B)(5)(c). For example, A.R.S. § 41-1035 requires agencies implementing rules to reduce the impacts on small businesses by using certain methods where legal and feasible. Methods that may be used include the following: (1) exempt them from any or all rule requirements; (2) establish performance standards which would replace any design or operational standards; or (3) institute reduced compliance or reporting requirements. The latter method could be accomplished by establishing less stringent requirements, consolidating or simplifying them, or by setting less stringent schedules or deadlines.

2. Examples of Flexibility and Cost Reductions

ADEQ has evaluated statutory methods and determined that it has used performance standards in this rule to the extent legal or feasible. ADEQ also has reduced compliance and reporting requirements for all entities affected by this rule to the extent legal or feasible. This rulemaking allows generators to make treatment decisions that are the most cost effective and least burdensome to them (refer to A.2., B.1., C.1., and E.). In addition, this rulemaking lists about 20 full or partial rule exemptions.

Generators can treat their biohazardous medical waste either on-site or off-site. Compared to off-site treatment/disposal costs, cost saving benefits could accrue to generators opting for on-site treatment, which could include alternative treatment technologies. A generator, for example, may treat cultures and stocks using microwave treatment even though the current treatment procedure is to either incinerate or autoclave cultures and stocks (refer to C.1.). This option is being made available to benefit small businesses. In addition, small businesses (probably small quantity generators of medical sharps) have several treatment/disposal options that could generate savings to them (refer to C.1. and E.1.). In addition, other classes of wastes may be treated by alternative treatment technologies, such as microwaving (refer to C.1.).

Although testing procedures to determine treatment efficacy (to confirm microbial inactivation) applies to a broad range of generators, small businesses are expected to benefit from this rule provision. For example, test strips of Bacillus subtilis or Bacillus stearothermophilus may be used, which are commercially available for purchase at relatively minimal prices. These spore strips are used by hospitals and other generators to test equipment for sterilizing biohazardous medical waste. The cost range for spore strips is $1.75 to $2.50. The cost for purchasing spore suspensions for testing would be greater. By simplifying treatment standards, ADEQ expects cost saving benefits to accrue to generators. In comparison, a reduced- or full-protocol test could range $2,000 to $5,000 or $20,000 to $25,000.

Another option allows generators to landfill untreated waste, provided the landfill accepts this waste stream and follows BMPs. This option especially was intended for those small generators located in rural areas that may not have access to off-site treaters at competitive prices (refer to A.2. and E.1.).

Finally, this rulemaking exempts individual households (self-care), as well as healthcare providers in private, public, or semi-public residences, unless such facilities are licensed by the Arizona Department of Health Services (refer to B.4.).

G. Employment/Revenues and Secondary Impacts

ADEQ does not expect this rulemaking to impact short-run or long-run employment, production, or output by healthcare facilities (both private and public entities). ADEQ does not expect profitability or capital availability to be affected. No categories of generators are expected to either close or reduce the level of services provided due to real-resource costs of complying with this rulemaking. Furthermore, this rulemaking is not expected to have an impact on state revenues.

Generally, there is no reason to believe that costs to consumers of healthcare services will increase as a result of costs passed on. This is mainly due to the overwhelming majority of generators currently treating and properly disposing of their biohazardous medical waste (the rulemaking codifies current industry standards and practices). The minority of generators that currently are not treating (inferred to be about 5%) or properly managing their waste should have a minimal impact on this industry as a whole. Of the few generators that are expected to be impacted, many have cost effective options available to them. And costs to some generators that may be impacted negatively would not be considered incremental (see Appendix C). The remaining proportion, although extremely small, could be negatively impacted by this rulemaking. In some cases, a generator, such as a hospital, may have to consider increasing costs, but this probably would represent the exception rather than the rule.

Table 1. Medical Waste Generators: Summary of mid-1995 Survey

Category of Generator	Estimated Number of Facilities a/	Estimated Sample Size (percent)	Average Amount of Waste (lbs./ mo) b/	Medical Sharps (percent of waste)	Average Cost to Treat (dollars/ mo)	Average Cost to Treat (dollars/ lb.) weighted ave.
Hospitals (includes on-site treatment)	110	44.5	11,497	18	2,218	.19
Hospitals (excludes on-site treatment)			12,356		2,574	.21
Nonhospital (includes all categories)			147		132	.90
Physicians' Offices and Clinics	4,185	2.8	199	43	162	.82
Dentists' Offices	1,632	1.9	6	65	36	5.88
Nursing and Long-Term Facilities	571	4.4	62	40	88	1.43
Veterinarians	362	1.4	56	61	48	.86
Funeral Homes/ Crematories	156	15.0	101	1	146	1.45
Laboratories	140	5.0	299	21	147	.49

Source: Number of facilities by generator category were derived from state data bases and data from the U.S. Department of Commerce. Other data computed from the generator survey conducted mid-1995. This table contains the result of revised data, including the reclassification of some generators. The nonhospital category includes home health agencies, which were exempted from this rulemaking. Also, sample size varies by category of generator and variable. For example, only 18 responses from dentists' offices were usable for estimating average costs.

a/ Nearly 65 percent of the generators would be classified as small businesses according to survey inferences.

b/ These generators produce an estimated 22.2 million pounds of biohazardous medical waste annually. Hospitals produce 2/3 of this amount, or 14.7 million pounds; nonhospital generators, comprising more than 98% of facilities, produce the remaining 7.5 million pounds (1/3 of total).

Appendix A

This appendix contains a very brief historical perspective.

The main focus of medical waste has been on hospitals and their management of infectious waste consisting of organs, hypodermic needles, and other contaminated materials. In the past, hospitals disposed of their infectious and pathological wastes by incinerating them on-site or by double-wrapping these wastes in red bags and simply landfilling them. A proportion of hospitals, and other facilities as well, have contracted with off-site treaters for treatment/disposal. However, this practice changed when landfill tipping fees increased and when landfills refused, or were reluctant, to accept any hospital waste. As a result, many hospitals incinerated both infectious and pathological wastes on-site.[23]

National events that occurred in the 1980s changed the management of medical waste. For example, the public suddenly became aware of the existence of medical waste as the news media reported on the alleged mismanagement of medical waste. Although the focus was on the eastern seaboard and the closure of beaches during tourist seasons, other incidents of improper disposal were dramatized in newspapers, magazines, TV news, and trade journals.[24] Another event was the acquired immune deficiency syndrome (AIDS) epidemic of the early 1980s.[25]

The public's fear of contracting AIDS from human immunodeficiency virus (HIV), and public fear of contagion in general, such as hepatitis B virus (HBV), have heightened the perception of risks associated with medical waste.[26] Much of the public's fear was likely a result of extensive media coverage of needles and syringes, and other wastes, washing up on beaches in Long Island and New Jersey, as well as being discovered in other locations in the late 1980s.[27] Most likely, this fear also was due to the public's lack of understanding of the principles of disease transmission.[28]

Reaction to these events created legislation and subsequent regulation of medical waste from 1 state to another. It can be documented that public and congressional concern concentrated on HIV and HBV as causative agents of diseases that potentially could be spread by medical waste.[29] In 1990 the State Legislature enacted Senate Bill 1407. The Legislature was concerned that the practice of medical waste management did not afford adequate protection to the workers inside and outside of the healthcare setting, as well as to the general public. The legislation required ADEQ to adopt rules that would regulate biohazardous medical waste, including medical sharps.

Appendix B

Numerous factors have acted as a catalyst, both independently and together, for generators to treat their biohazardous medical waste in absence of a regulatory program in Arizona. Inferences from ADEQ's mid-1995 generator survey revealed biohazardous medical waste being treated at an overall rate greater than what may have been expected. The following statements summarize these factors:

1. National attention has been focused on the management of medical waste, beginning more than a decade ago when medical waste appeared on beaches and in other public places.
2. The Medical Waste Tracking Act of 1988, a 2-year demonstration program to track medical waste in certain eastern states (1989-1991), was implemented by the EPA. Additionally, the Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, has been mandated by Congress to prepare a report on the health effects of medical waste.
3. The regulated industry and public have anticipated since the early 1990s that ADEQ would promulgate medical waste rules.
4. The Arizona Department of Health Services has promulgated rules which require Arizona's hospitals to treat potentially hazardous medical waste (1979).[30]
5. Most municipal solid waste landfills in Arizona have refused to accept untreated biohazardous medical waste.
6. The federal Occupational Safety and Health administration (OSHA) has promulgated occupational exposure standards to protect worker health and safety.
7. The EPA Office of Technology Assessment has published a guide for the management of infectious medical wastes (1986). This guide was published as a draft manual in 1982.
8. The Centers for Disease Control has published several medical waste management documents on hospital waste (1983, 1985, 1987, and 1988).

9. National professional associations, commissions, and societies have advanced various guidelines for the healthcare industry (such as, American Hospital Association, Joint Commission on Accreditation of Healthcare Organizations, and State and Territorial Association on Alternative Treatment Technologies).
10. The U.S. Army had regulations that addressed hospital and laboratory wastes in the early 1960s. Infectious wastes had to be segregated and treated by incineration (included experimental animal wastes, laboratory tissue specimens and infectious wastes).
11. Off-site treaters aggressively have marketed their services to all categories of generators and convinced many that they need to have their biohazardous medical waste treated.

Appendix C

This appendix contains a brief presentation about incremental impacts.

The term "incremental impact" means probable costs and benefits that would occur as a result of this rulemaking becoming effective compared to the costs and benefits in absence of it. This means that a baseline must be selected to which future costs and benefits can be assessed. Any past expenditures or future ones incurred regardless of this rulemaking, and prior benefits or future ones that would be received without this rulemaking, would not be considered incremental impacts.

The incremental impact is measured against a selected baseline, and the impact also should include expected benefits. A baseline should represent the most likely situation in the industry in absence of a rulemaking. For this rulemaking, the selected baseline is based on the assumption that the present industry trend will continue in absence of the rulemaking. This is a trend in which the proportion of generators properly packaging and treating their biohazardous medical waste is increasing. Even if this trend reaches a saturation point, whereby the status quo will be maintained, the industry trend is viewed as increased treatment. An alternative assumption, which predicts current industry trends will shift due to changes in relative prices of inputs used in production or technological changes or other regulations, is unlikely, and hence, was not selected.

The examples which follow were reported by respondents that participated in the mid-1995 generator survey. A county health department, which operates 4 outpatient clinic services employing 170 persons, reported annual expenditures of nearly $3,400 for having its biohazardous medical waste packaged and treated. This includes the cost of purchasing sharps containers plus the cost to have an off-site treater pick up and treat its waste. This does not include the cost to purchase red bags and containers. A hospital, which employs 2,000 persons, reported annual expenditures of $82,800 to have its biohazardous medical waste picked up and treated by an off-site treater. Likewise, a dental office reported an annual cost of $420 to have its biohazardous medical waste treated off-site. A few generators reported they were searching for an off-site treater to have their waste treated for which they would incur a future cost. A rural hospital, which formerly contracted with an off-site treater to have its waste treated, decided to save money and transport its untreated biohazardous medical waste to a nearby landfill for disposal. However, hospital staff indicated that once this rulemaking was effective, the hospital would again contract with an off-site treater and pay the additional cost. None of these generators, except for perhaps the last one, would generate expenditures that would represent incremental costs of this rulemaking.

Endnotes

[1] STAATT, 1994, p. 5; Turner, 1997; Byrns and Burke, 1992; LaMoreaux and Green, 1990; and Clark, 1989. Turner (1997) suggests that the management of medical waste, including treatment standards, should conform to other states so that a particular state would not be viewed as an attractive disposal grounds (low-cost).

[2] U.S. DHHS, 1990 (specifically see pp. E.9, E.3, and 2.13).

[3] Potential benefits could accrue to refuse workers and landfill personnel. Potentially, these occupational subgroups could experience a reduction in work-related injury rates from medical sharps. Logically, this is possible if fewer medical sharps are inappropriately managed because this would increase the opportunity for injury and infection for certain occupational subgroups. For instance, data from a decade ago show that 7,300 injuries to refuse workers were associated with medical waste sharps and only 14% (about 1,000) were due to publicly generated medical waste. Furthermore, injury rates from medical sharps, which were calculated from 2 studies, showed waste handling facility rates were at 20.4 and 23.8 per 1,000 workers. The highest rates were calculated for "handlers" at 36.3 and 24.0 per 1,000 workers. Note that both patient-care workers and non-patient-care workers sustained medical sharps injuries. The overall rates for all healthcare facilities were 19.5 and 14.2 per 1,000 workers with the highest rates among laboratory workers and housekeepers (see U.S. DHHS, 1990, pp. E.5, E.11, 5.2, 5.7-5.19, and 6.1-6.3 for information about injury rates).

[4] According to past Centers for Disease Control data, 200 to 300 healthcare workers, including waste handlers, die each year of hepatitis B virus (HBV) they contact on the job (see Cheremisinoff, 1990, p. 79 and 62 FR 64002 (Dec. 6, 1991).

[5] Keene, 1989, p. 683; Moore, 1989; and Rutala and Mayhall, 1992.

[6] Rutala and Weber, 1991.

[7] U.S. DHHS, 1990, pp. 10.1 and E.9. Note that the HIV is a retrovirus that inactivates T-cells and is a cause of AIDS.

[8] U.S. DHHS, 1990, pp. E.3 and E. 9 (also see p. E.4). Communicable diseases, theoretically, have the potential to be transmitted to humans. Various diseases, common and self-limiting ones and more serious and less common diseases, could be contracted from medical waste both inside and outside of the healthcare setting, including medical waste disposed in the residential solid waste stream. However, measuring injuries and infections is very difficult and subject to biases (see U.S. DHHS, 1990, pp. 2.11 and 2.12).

[9] Other occupational subgroups inside the healthcare setting (nurses, laboratory workers, engineers, maintenance workers, janitors, and laundry workers) are subject to elevated risks. But under this rulemaking, any impacts to these subgroups would not be considered incremental since this rulemaking will regulate biohazardous medical waste once it is discarded. Even so, various occupational subgroups (nursing staff, janitors, housekeepers, refuse haulers, and landfill personnel, etc.) could be at risk, particularly for exposure to HBV. These subgroups could encounter medical sharps due to improper disposal or to accidental exposure. Likewise, they could be faced with the potential for disease transmission from other biohazardous medical waste, such as cultures and stocks, not properly handled or treated. See Cheremisinoff, 1990; Sullivan, 1988; Clark, 1989; and U.S. DHHS, 1990, pp. E.9 and 10.1.

The occupational exposure risk for a healthcare worker depends on the immune status of the worker as well as other factors. Personal protective equipment (PPE) diminishes the potential for disease, but does not eliminate it. Other factors include training, exposure control planning, and housekeeping practices. It also should be noted that the risk for HB infections is lower now than in the past due to PPE and other protocols followed by healthcare workers. However, HB disease is not always correctly diagnosed or reported and the person infected may not even know it. In addition to HBV, the C virus (HCV), which is generally referred to as non-A and non-B hepatitis, is of concern to healthcare workers. The relative infectivity of HCV in blood may be 100 to 100,000 times lower than with HBV (see 56 FR 64013; also 64026-64032, 64035).

[10] Rutala and Mayhall, 1992; Clark, 1989; Turnberg, 1991; and Rutala and Weber, 1991.

[11] Clark, 1989.

[12] McKone and Bogen, 1991.

[13] U.S. DHHS, 1990, pp. 6.2, 7.8, and 2.12. Note that blood and blood components can contain bloodborne infectious agents, such as HBV. See also Turnberg, 1991, p. 23.

[14] Möse and Reinthaler, 1985. They found that household waste was more contaminated quantitatively, particularly with fecal bacteria. They also noted that 2% of all blood-drenched waste and serum samples were anti-HB_c and anti-HB_e positive (indicating the presence of the HBV).

[15] The primary data source of this EIS is the generator survey that was conducted mid-year 1995. A stratified, random sample methodology was used to reduce sampling bias and to improve the reliability and validity of the survey. ADEQ mailed surveys to more than 1,000 generators out of an estimated universe of about 7,290 generators. The overall sample size was relatively small at 3.7 percent. although that proportion changed by the variable analyzed. The 1995-generator survey included home health agencies (134), but they are exempted from this rulemaking. Other data sources include conversations with treaters, pharmacies, state associations (Arizona Hospital and Healthcare Association and Arizona Dental Association), companies which sell mail-back kits for sharps disposal, and a company which sells a system to encapsulate sharps. Note also, in September of 1995, ADEQ sent a treater survey to 4 treaters and 2 transporters who had established businesses in the state, as well as 1 treater located in New Mexico that transports waste out of Arizona. None of the treaters or transporters responded to that survey. However, since that time the market has changed due to business acquisitions. Currently, only 1 major off-site treater is operating in Arizona.

[16] As pointed out in the proposed EIS, the 5% proportion of generators not treating/disposing their biohazardous medical waste may be understated which would underestimate the compliance cost. This caveat is due to the small

sample size of the mid-1995 generator survey and other factors, such as non-response bias and other sampling errors and biases. ADEQ presupposes that during the 1990s, the proportion of generators treating their waste was increasing.

[17] Compare this to landfill tipping fees for solid waste which range from $25.00 to $30.00 per ton or $0.0125 to $0.015 per pound. This is not to say that landfill owners/operators will charge this amount for untreated biohazardous medical waste disposed of in their landfills. Note that a landfill does not have to accept untreated biohazardous medical waste.

[18] U.S. DHHS, 1990, pp. 10.1-10.3.

[19] Additional examples include: outpatient clinics, ambulatory surgical centers, blood banks, dialysis centers, community health centers, infirmaries, migrant health clinics, HMO medical offices, ophthalmology clinics, student health centers, behavioral health services, medical laboratories, and research facilities.

[20] Based on previously acquired data, a generator could purchase a mail-back kit containing 4 "one gallon" medical sharps containers for $133.50. The cost per liter would be about $8.34, and if the containers lasted 6 months, the monthly cost would be $22.25. In comparison, a generator could purchase 6 "2.5 liter" encapsulation containers for $87.76. The cost per liter would be about $5.85, and if the containers lasted 6 months, the monthly cost would be $14.63. The equivalent monthly cost would vary by the size of container and the amount of sharps generated. Table 1 shows the monthly costs by category of generator. The monthly average for dentists' offices is $36.

[21] U.S. DHHS, 1990, pp. 7.8-7.9. Microbiological content also is reduced by secondary treatment methods.

[22] The 2 most significant bloodborne pathogens are HBV and HIV. However, there are other bloodborne pathogens of concern, such as hepatitis C virus (HCV), syphilis and malaria, and several others that cause diseases but which are rare in the U.S. This latter group includes: Babesiosis, Brucellosis, Leptospirosis, arboviral infections (Colorado tick fever), relapsing fever (pathogenic Borreliae), Creutzfeldt-Jakob, human T-lymphotropic virus Type I, and viral hemorrhagic fever (56 FR 64022-64023).

[23] Tessitore and Cross, 1988, p. 83. Also see C.C. Lee, et al.; and U.S. DHHS, 1990, p. 7.4. Note also that the healthcare industry switched from recyclables to disposables for infection control reasons. This caused an increase in the volume of medical waste to be disposed (Byrns and Burke, 1992, p. 14 and Bruning, 1992).

[24] Burke, 1994, p. 11; Uzych, 1990, p. 233; Cheremisinoff, 1990; Calmbacher, 1989; and Moore, 1989.

[25] Naber, 1989; Roy, 1989; Byrns and Burke, 1992; and Keene, 1989. Note that municipal and private waste management officials began asking: "Is AIDS in the red bag? How can we protect our employees from it?" They complained that red bags containing medical waste (hypodermic needles, bloodied instruments, surgical dressings, blood vials, etc.) were being found with solid wastes headed for landfills (see Naber, 1989, p. 89).

[26] According to Centers for Disease Control (CDC), the AIDS virus is fragile and dies quickly when exposed to the environment. However, hepatitis B virus (HBV) can survive in dried blood for as long as several weeks. The risk to HBV is more of an occupational exposure risk for certain subgroups rather than a health threat to the general public. (Cheremisinoff, 1990, p. 78; and U.S. DHHS, 1990, pp. E.1, E.3, E.6-E.8, 1.1, 2.11-2.20, 4.4-4.10, 5.3-5.25, 6.1-6.3, 10.1-10.5).

[27] The broad media coverage exploited the topic of waste management. The media reported numerous incidents of the public and waste handlers coming in contact with medical waste, including children playing with vials of AIDS infected blood from an unlocked dumpster outside of several physicians' offices. Numerous journal articles, for example, report incidents of "infectious waste" affecting the public and certain workers contacting medical wastes during the course of their workday. Medical wastes also were being found on city streets, in ditches, and in refuse containers (see Clark, 1989, p. 206; Etter, et al., 1990, p. 77; Lee, et al., 1991, p. 360; Naber, 1989, p. 89; and Moore, 1989, p. 34). However, the main problem along the eastern seaboard, particularly New York and New Jersey, simply was litter. Medical waste did not even constitute 99% of the total. Combined sewer overflows, stormwater runoff, and marine transfer stations were the sources of the debris washing up on the beaches (see Cameron and Jijina, 1990).

[28] Rutala and Mayhall, 1992.

[29] U.S. DHHS, 1990, pp. E.3 and 2.11.

[30] The Arizona Department of Health Services has promulgated rules (1979) which require Arizona's hospitals to treat potentially hazardous medical waste, except as provided by rule. Hospitals also must meet standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Essentially, the 1988 JCAHO accreditation standard requires hospitals to do the following: (1) control their waste from point of origin to final disposal; (2) protect patients, personnel, and the environment; (3) develop procedures for managing hazardous materials; and (4) provide for the safe handling and disposal of hazardous waste. In addition, the federal Occupational Safety and Health Administration (OSHA) has promulgated occupational exposure standards to protect worker health and safety (bloodborne pathogen standard). The purpose of the standard is to limit occupational exposure from infectious materials that could result in transmission of bloodborne pathogens. It covers all employees who could be reasonably anticipated to come into contact with blood or other potentially infectious materials due to the performance of their job duties. It is not just restricted to the healthcare industry. Finally, a variety of other entities (Centers for Disease Control, EPA, American Hospital Association, National Governors Association, American Medical Association, and American Hospital Care Association), which set standards and guidelines, or that certify, all play a role in ensuring healthcare facilities are safe (see Uzych, 1990, p. 235; 29 CFR Part 1910; and U.S. Dept. of Commerce, 1994, p. 42-5).

References

Bruning, Lois M. "Disposables v. Reusables in OR Practices: Part II, Weighing Costs, Risks and Wastes." *Nursing Management* 23 (March 1992): 72I-72P.

Burke, Ester L. "A Survey of Recent Literature on Medical Waste." *Journal of Environmental Health* 56 (May 1994): 11-14.

Byrns, George, and Thomas Burke. "Medical Waste Management Implications for Small Medical Facilities" *Journal of Environmental Health* 55 (Nov./Dec. 1992): 12-15.

Calmbacher, C.W. "Diagnosis Pending For Medical Waste." *Environmental Protection* (5/93): 22-23, 25-26.

Cameron, John D. Jr., and Janice Jijina. "The WPCA Long Island Chapter Acts on Beach Debris." *Water Environment & Technology* (June 1990): 44-47).

Cheremisinoff, Paul N. "Focus on High Hazard Pollutants." *Pollution Engineering* 22 (Feb. 1990): 67-79.

Clark, Richard. "Infectious Waste: A Survey of Handling Practices in Lincoln, Nebraska." *Journal of Environmental Health* 51 (March/April 1989): 206-208.

Etter, Roger G.; Kiser, Jonathan V. L.; and Shuler, Stephen E. "Medical Waste Combustion: Current And Future Prospects." *Waste Age* 21 (July 1990): 77-78, 80.

Keene, John H. 1989. "Medical Waste Management: Public Pressure Versus Sound Science. *Hazardous Materials Control* 2 (September/October): 29-31, 34,36.

LaMoreaux, James W., and Nancy Green. "Risk Assessment in Managing Infectious Wastes." *Water Environment and Technology* 2 (June 1990): 40-43.

Lee, C. C.; Huffman, George L.; and Nalesnik, Richard P. "Medical Waste Management: The State of the Art." *Environ. Sci. Technol*. 25 (March 1991): 360-363.

McKone, Thomas E., and Kenneth T. Bogen. 1991. "Predicting the Uncertainties in Risk Assessment." *Environmental Science Technology* 25 (October): 1674-1681.

Moore, John A. "The Plan for Medical Wastes." *Waste Age* 20 (February 1989): 34-38.

Möse, Josef R., and Franz Reinthaler. 1985. "Mikrobiologische Untersuchungen zur Kontamination von Karankenhausabfällen und Haushaltsmüll." *Zbl. Bakt. Hyg.*, Abt. Orig. B 181, 89-110.

Naber, Thomas. "Infectious Wastes: The Questions Remain." *Waste Age* 20 (May 1989): 89-94.

Roy, Kimberly A. "Medical Waste Incineration: Tighter Regulations Spark Renewed Interest in Incineration." *Hazmat World* (June 1989): 17-21.

Rutala, William A., and C. Glen Mayhall. "Medical Waste" (The Society for Hospital Epidemiology of America Position Paper). *Infection Control & Hospital Epidemiology*13 (Jan.92): 38-48.

Rutala, William A., and David J. Weber. "Infectious Waste-Mismatch between Science and Policy." (Sounding Board) *The New England Journal of Medicine* 325 (August 22, 1991): 578-582.

State and Territorial Association on Alternative Treatment Technologies (STAATT). *Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies.* April 1994, p. 5.

Sullivan, Thomas F. P. "Medical Waste: The Latest Waste Management Issue." *Pollution Engineering* 20 (Dec. 1988): 42-44,46.

Tessitore, Joseph L., and Frank L. Cross. ""Incineration of Hospital Infectious Waste." *Pollution Engineering* 20 (November 1988): 83-88.

Turnberg, Wayne L. "Infectious Waste Disposal: An Examination of Current Practices and Risks Posed." *Journal of Environmental Health* 53 (May/June 1991): 21-25.

Turner, John H. "Closing the Loop of State Medical Waste Regulation." *Environmental Regulation and Permitting* 6 (Spring 1997): 57-69.

U.S. Department of Commerce. International Trade Association. *U.S. Industrial Outlook*, 1994.

U.S. Department of Health and Human Services (U.S. DHHS). Agency for Toxic Substances and Disease Registry. 1990. *The Public Health Implications of Medical Waste: A Report to Congress*. Atlanta, Georgia.

Uzych, Leo. "Medical Waste Management: Regulatory issues and Current Legal Requirements." *Journal of Environmental Health* 52 (January/February 1990): 233-235.

29 CFR Part 1910.

62 FR 64002 (Dec. 6, 1991) Bloodborne Pathogens Standard (final rule).

10. A description of the changes between the proposed rule, including supplemental notices and final rules (if applicable):

Article 14 has been revised for clarity, conciseness, understanding, and in response to comments as follows. Rule text which remains unchanged from the proposed rule is not repeated here, but is indicated as "..."

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:

...

2. "Alternative treatment technology" means a treatment method other than autoclaving or incineration, that achieves the treatment standards described in R18-13-1415.
3. "Approved medical waste facility plan" means the document that has been approved by the Department under A.R.S. § 49-762.04, and that authorizes the operator to accept ~~regulated~~ biohazardous medical waste at its solid waste facility.
4. "Autoclaving," ~~or steam sterilization, means the act or process of achieving complete elimination or destruction of all forms of microbial life.~~ means using a combination of heat, steam, pressure, and time to achieve sterile conditions.
5. "Biohazardous medical waste" ~~or "regulated medical waste" means that component of medical waste as defined in A.R.S. § 49-701 that is likely to transmit etiologic agent and~~ is composed of 1 or more of the following:
   a. ~~Cultures and stocks: Cultures and stocks of infectious agents and associated biologicals including cultures from medical and pathological laboratories, cultures and stock of infectious agents from research and industrial laboratories, waste from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.~~
   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. ~~Waste human blood and blood products: Discarded waste human blood and blood products, and material containing free-flowing blood and blood components.~~
   b. Human blood and blood products: Discarded products and materials containing free-flowing blood or free-flowing blood components.
   c. ~~Pathological wastes: Human pathological wastes, including tissues, organs, body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.~~
   c. Human pathologic wastes: Discarded organs and body parts removed during surgery. Human pathologic wastes do not include the head or spinal column.
   d. ~~Medical sharps: Discarded sharps, whether used or unused, in animal or human patient care or treatment or in medical research or industrial laboratories, including hypodermic needles, syringes, Pasteur pipettes, glass contaminated with blood or specimen, and scalpel blades.~~

d. Medical sharps: Discarded sharps used in animal or human patient care, medical research, or clinical laboratories. This includes hypodermic needles; syringes; pipettes; scalpel blades; blood vials; needles attached to tubing; broken and unbroken glassware; and slides and coverslips.

~~e. Research animal wastes: Animal carcasses, body parts and bedding of animals that, during the research and production of biologicals, or testing of pharmaceuticals, are exposed to or contaminated by infectious agents that are pathogenic to healthy humans.~~

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. Isolation wastes: Biohazardous medical wastes containing discarded materials contaminated with blood, excretion, or exudates, or secretions from humans who are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or isolated animals known to be infected with diseases that are highly communicable to humans.~~

...

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 ~~licensed~~ products.

~~9. "Body fluids" means any substance that emanates or derives from the human body including: tissue, semen, vaginal secretions, cerebro-spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Feces, nasal secretions, sputum, sweat, tears, urine, or vomitus are "body fluids" for the purposes of this Article only if they contain visible blood.~~

...

~~12. "Collection" means the pick-up of regulated medical waste from the generator's waste accumulation or storage area by a transporter for the purpose of transport the waste away from the generator's facility to a Department approved medical waste storage, treatment, or disposal facility. Collection does not include waste pick-up by a janitorial service that occurs within the generator's place of business, if the waste is not removed from the generator's place of business.~~

~~13. "Contaminate" or "contamination" means to soil, stain or infect by the transfer of blood or other matter that may contain infectious agents.~~

~~14. "Decontaminate" or "decontamination" means the process of reducing or eliminating the presence of infectious substances, in order to reduce the likelihood of disease transmission from those substances by exposure to hot water of at least 180° F. for a minimum of 15 seconds, or by exposure to mixture of cold water and a disinfectant.~~

~~15.~~11. "Dedicated vehicle" means a motor vehicle or trailer that is pulled by a motor vehicle ~~and that is~~ used by a transporter for the sole purpose of transporting ~~regulated~~ biohazardous medical waste.

~~16.~~12. "Discarded drug" means any prescription medicine, over-the-counter medicine, or controlled substance, used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to ~~dispose~~ abandon. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.

~~17.~~13. "Disposal facility" means a municipal solid waste landfill that has been approved by the Department under A.R.S. § 49-762.04 to accept untreated ~~regulated~~ biohazardous medical waste for disposal.

~~18.~~14. "Facility plan" has the meaning given to it in A.R.S. § 49-701.

~~19.~~15. "Free flowing" means ~~any~~ liquid ~~which~~ that separates readily from any portion of a ~~regulated~~ biohazardous medical waste under ambient temperature and pressure.

~~20.~~16. "Generator" means a person whose act or process produces ~~regulated~~ biohazardous medical waste, or a discarded drug, or whose act 1st causes a ~~regulated~~ medical waste or a discarded drug to become subject to regulation.

~~21. "Hard-plastic or metal container" means a "medical sharps container" as defined below or a heavy plastic container such as liquid detergent bottle that has a screw on lid or a tightly secured lid.~~

~~22.~~17. "Hazardous waste" has the meaning prescribed in A.R.S. § 49-921~~(5)~~.

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

~~23.~~19. "Improper disposal of ~~regulated~~ biohazardous medical waste" means the disposal by a person of untreated or inadequately treated ~~regulated~~ biohazardous medical waste at any place that is not approved to accept untreated ~~regulated~~ biohazardous medical waste.

~~24.~~20. "Independent testing laboratory" means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.

~~25. "Infectious agent" means a type of microorganism, bacteria, mold, parasite, or virus that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.~~

~~26.~~21. "Medical sharps container" means a vessel that is rigid, puncture resistant, leak proof, and equipped with a locking cap.

~~27. "Medical sharps waste" means any medical device having acute rigid corners, edges, or protuberances capable of cutting or piercing, including but not limited to, all of the following:~~
~~a. Hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, syringes contaminated with biohazardous waste, acupuncture needles, and root canal files.~~
~~b. Broken glass items, such as Pasteur pipettes and blood vials contaminated with regulated medical waste.~~
~~28.~~22. "Medical waste," as defined in A.R.S. § 49-701, means "*any solid waste which is generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biologicals, and includes discarded drugs but does not include hazardous waste as defined in A.R.S. § 49-921(~~5~~) other than conditionally exempt small quantity generator waste*."
~~29.~~23. "Medical waste treatment facility" or "treatment facility" means a solid waste facility approved by the Department under A.R.S. § 49-762.04 to accept and treat ~~regulated~~ biohazardous medical waste from off -site generators.
~~30.~~24. "Multi-purpose vehicle" means ~~a car, van or truck~~ any motor vehicle operated by a ~~public~~ health ~~public~~ care worker, where the general purpose ~~for which~~ 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 ~~regulated~~ biohazardous medical waste generated off site by ~~public~~ health workers in providing services. "Off site" for purposes of this definition means a location other than a hospital or clinic.
~~31.~~25. "Off site" means a location that does not fall within the definition of "on site" ~~described~~ contained in A.R.S. § 49-701(~~23~~).
~~32.~~26. "Packaging" or "properly packaged" means the use of a container or a practice under R18-13-1407.
~~33.~~27. "Putrescible waste" means waste materials capable of being decomposed rapidly by microorganisms.
~~34.~~28. "Radioactive material" has the meaning under A.R.S. § 30-651.
~~35. "Regulated medical waste" means biohazardous medical waste, medical sharps waste, and discarded drugs.~~
~~36.~~29. "Secure" means to lock out or otherwise restrict access to unauthorized personnel.
~~37.~~30. "Spill" means either of the following:
a. Any release of ~~regulated~~ biohazardous medical waste from its package while in the generator's storage area.
b. Any release of ~~regulated~~ biohazardous medical waste from its package or the release of packaged ~~regulated~~ biohazardous medical waste by the transporter at a place or site that is not a medical waste treatment or disposal facility.
~~38. "Sterilization" means the complete elimination or destruction of all forms of microbial life.~~
~~39.~~31. "Store" or "storage" means, in addition to the meaning under A.R.S. § 49-701, either of the following:
a. The temporary holding of properly packaged ~~regulated~~ biohazardous medical waste by a generator in a designated accumulation area awaiting collection by a transporter.
b. The temporary holding of properly packaged ~~regulated~~ biohazardous medical waste by a transporter or a treater at an approved medical waste storage facility or treatment facility.
~~40.~~32. "Technology provider" means a ~~corporation~~ person that manufactures, or a vendor who supplies alternative medical waste treatment technology.
~~41.~~33. "Tracking document" means the written instrument ~~which~~ that signifies acceptance of ~~regulated~~ biohazardous medical waste by a transporter, or a transfer, storage, treatment, or disposal facility operator.
~~42.~~34. "Transportation management plan" means the transporter's written plan consisting of both of the following:
a. The procedures used by the transporter to minimize the exposure to employees and the general public to ~~regulated~~ biohazardous medical waste throughout the process of collecting, transporting, and handling.
b. The emergency procedures used by the transporter for handling spills or accidents.
~~43.~~35. "Transporter" means a person engaged in the hauling of ~~regulated~~ biohazardous medical waste from the point of generation to a~~n~~ ~~intermediate~~ Department- approved storage facility or to ~~an~~ a Department- approved treatment or disposal facility.
~~44.~~36. "Treat" or "treatment" means, with respect to the methods used to render biohazardous medical waste less infectious: incinerating, autoclaving, or using the alternative treatment technologies prescribed in this Article.
~~45.~~37. "Treated medical waste" means ~~regulated~~ 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. ~~and may be disposed of in a municipal solid waste landfill.~~
~~46.~~38. "Treater" means a person, also known as an operator, who receives solid waste facility plan approval for the purpose of operating a medical waste treatment facility to treat ~~regulated~~ biohazardous medical waste that was generated off site.
~~47.~~39. "Treatment certification statement" means the written document provided by either a generator who treats ~~regulated~~ biohazardous medical waste on site or by a treater, to inform a solid waste disposal or recycling facility that ~~regulated~~ biohazardous medical waste has been treated as prescribed in this Article, and therefore is no longer subject to regulation under this Article.
~~48.~~40. "Treatment standards" ~~means~~ mean the ~~level~~ levels of microbial inactivation, prescribed in R18-13-1415, to be achieved for a specific type of ~~regulated~~ biohazardous medical waste ~~as required by this Article~~.

~~49.~~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.

~~50. "Vehicle not dedicated to the transportation of regulated medical waste but which is engaged in commerce" means a motor vehicle or a trailer that is pulled by a motor vehicle, that is, used on a temporary basis for the transportation of regulated medical waste, and that has the primary purpose of transporting of goods that are not solid waste or regulated biohazardous medical waste~~.

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

R18-13-1402. Applicability

A. This Article applies to the following:

1. A generator who treats ~~regulated~~ biohazardous medical waste on site, before disposing of it as treated medical waste, and to any equipment used for that purpose. ~~A generator who treats on-site shall meet the requirements in R18-13-1405.~~ Specific requirements for a generator who treats on site are prescribed in R18-13-1405.
2. A generator who contracts with a medical waste treatment facility for the purpose of treating ~~regulated~~ biohazardous medical waste. ~~This generator shall meet the requirements of R18-13-1406.~~ Specific requirements for such a generator are prescribed in R18-13-1406.
3. A person who transports ~~regulated~~ biohazardous medical waste and any motor vehicle used for that purpose.

...

6. A person in possession of ~~regulated~~ biohazardous medical waste if the waste does not meet the treatment standards in R18-13-1415.
7. An operator of a ~~municipal solid waste landfill~~ Department-approved disposal facility who accepts untreated ~~regulated~~ biohazardous medical waste.
8. A person who generates medical sharps in the preparation of human remains.
9. A person who generates medical sharps in the treatment of animals.
10. A generator of discarded drugs not returned to the manufacturer.

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

~~**C.** Treated medical waste is considered solid waste as described in A.R.S. Title 49, Chapter 4.~~

R18-13-1403. Exemptions; Partial Exemptions

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

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

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

1. A person who prepares ~~Human~~ 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 if the ~~regulated~~ biohazardous medical waste is ~~transported to a central collection facility~~ returned to the home facility for disposal. ~~The central collection facility~~ This facility is considered to be the point of generation for packaging, treatment, and disposal.

~~3. A person who sends used medical sharps to a treatment facility if properly packaged and transported via the United States Postal Service or private shipping agent.~~

~~4.~~3. A person who discharges discarded drugs and liquid and semi-liquid ~~regulated~~ 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.

~~5.~~4. A person who possesses hazardous waste regulated by A.R.S. Title 49, Chapter 5.

~~6. A person who resides in a private, public, or semi-public residence and who generates regulated medical waste in the administration of self-care. This exemption does not apply to a person residing in a facility licensed by the Arizona Department of Health Services.~~

5. A ~~public~~ health care worker who uses a multi-purpose vehicle in the conduct of routine business other than transporting waste, is exempt from the requirements of R18-13-1409 if the health care worker complies with all of the following:
   a. Packages the ~~regulated~~ biohazardous medical waste according to R18-13-1407.
   b. Secures the packaged ~~regulated~~ biohazardous medical waste within the vehicle so as to minimize spills.
   c. Transports the ~~regulated~~ biohazardous medical waste to the ~~agency's central collection site~~ place of business or to a medical waste treatment or disposal facility.
   d. ~~Decontaminates~~ Cleans the vehicle when it shows visible signs of contamination.
   e. Secures the vehicle to prevent unauthorized contact with the ~~regulated~~ biohazardous medical waste.

6. A person who transports ~~regulated~~ biohazardous medical waste between multiple properties separated by a public thoroughfare and which is owned or operated by the same owner or governmental entity is exempt from the requirements of ~~R18-13-1407~~ R18-13-1409 if the person complies with ~~subsection 7~~ R18-13-1403(B)(5) (a)-(e).

7. A hospital that chooses to accept medical sharps from staff physicians who generate medical sharps in a private practice is exempt from the requirement to obtain facility plan approval as long as the hospital collects medical sharps for off-site treatment or disposal.

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

1. A generator who treats ~~regulated~~ biohazardous medical waste on-site and who accepts for treatment ~~medical waste described in paragraph(B)(6) of this section~~ medical waste described in R18-13-1403(A)(4) is exempt from the requirement to obtain solid waste facility plan approval ~~described~~ prescribed in R18-13-1410.

~~2. A generator who contracts with a permitted transporter to transport regulated medical waste to a medical waste treatment or disposal facility is relieved of any obligation to retrieve and treat improperly disposed regulated medical waste after the transporter accepts possession.~~

~~3. A generator who self-hauls regulated medical waste to an approved medical waste treatment or disposal facility is relieved of any obligation to retrieve and treat regulated medical waste that is improperly disposed, after the treater or landfill operator accepts possession.~~

2. A generator who self-hauls biohazardous medical waste to a Department-approved medical waste treatment, storage, transfer, or disposal facility is exempt from the requirements of R18-13-1409 if the generator complies with R18-13-1403(B)(5)(a)-(e).

~~4. A person who is in possession of regulated medical waste that also contains radioactive material is exempt from the packaging and storage requirements of this Article if the packaging and storage requirements of A.A.C. R12-1-101 through R12-1-112 are more restrictive. A person shall not treat and dispose of biohazardous medical waste until after the radioactive component has decayed in storage as provided in A.A.C. R12-1-101 through R12-1-112.~~

R18-13-1404. Transition and Compliance Dates

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 ~~regulated~~ biohazardous medical waste is the effective date of this Article.

B. A person who provides alternative medical waste treatment technology ~~in operation~~ 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 ~~described~~ prescribed in R18-13-1414 within 90 days after the effective date of this Article.

~~2. After 90 days of the effective date of this Article, not provide alternative medical waste treatment technology to additional generators until Departmental registration is received.~~

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 ~~is received~~, provide to all generators using the alternative treatment technology a copy of the registration ~~certification~~ certificate and the alternative technology manufacturer's specifications. ~~as required in R18-13-1414~~.

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, ~~as~~ 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 ~~regulated~~ biohazardous medical waste treated 180 days after

the effective date of this Article using the unregistered alternative treatment technology ~~is considered to be~~ as untreated ~~regulated~~ biohazardous medical waste.

D. A generator who utilizes incineration or ~~steam sterilization~~ autoclaving for on-site treatment of ~~regulated~~ 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 on-site treatment requirements of R18-13-1405 are met.

E. A transporter of ~~regulated~~ biohazardous medical waste ~~before~~ 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 ~~as~~ for a solid waste facility ~~as described by~~ under A.R.S. § 49-762.04 ~~and who has obtained that approval~~ on or before the effective date of this Article, may continue to store ~~regulated~~ biohazardous medical waste if the facility complies with the design and operation standards ~~described~~ 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 ~~must~~ 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 ~~and who has obtained that approval~~ 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 paragraph below.
2. If the treater determines that the waste is not being treated to the applicable treatment standards of R18-13-1415, the treater ~~shall inform~~ informs the Department within 2 working days ~~of this~~ after the date on the determination, and within 30 working days ~~enter~~ 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 ~~regulated~~ biohazardous medical waste shall submit a notice of a Type ~~3~~ 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 ~~receiving~~ the date on the Department's determination. The treater may continue to operate under the conditions specified in subsection ~~(F)~~ (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.~~03~~.04 is required for a new medical waste treatment or disposal facility before construction.

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

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

B. A generator who uses:

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

C. A generator who incinerates ~~regulated~~ biohazardous medical waste on site shall comply with all of the following ~~conditions~~ requirements:

1. Obtain a permit if required by the local or state air quality agency having jurisdiction.
2. Reduce the ~~regulated~~ biohazardous medical waste, excluding metallic items, into carbonized or mineralized ash.
3. ~~Perform a waste determination of~~ Determine whether incinerator ash is hazardous waste as required by hazardous waste rules ~~adopted~~ promulgated under A.R.S. Title 49, Chapter 5.
4. Dispose of the non-hazardous waste incinerator ash at a Department-approved municipal solid waste landfill.

D. A generator who autoclaves biohazardous medical waste on site shall comply with all of the following ~~conditions~~ requirements:

1. Further process by grinding, shredding, or any other process, any recognizable animals and human tissue, organs, or body parts, ~~and animals~~ to render such waste non-recognizable and ~~suitable for treatment~~ ensure effective treatment.
2. Operate the autoclave at the manufacturer's specifications appropriate for the quantity and density of the load ~~and sufficient to achieve sterilization, as defined in R18-13-1401.~~
3. Keep records of operational performance levels for 6 months after each treatment cycle. Operational performance level recordkeeping ~~shall include~~ includes all of the following:
   a. Duration of time for each treatment cycle.
   b. The temperature and pressure maintained in the treatment unit during each cycle.
   c. The method used to determine treatment parameters ~~as set forth~~ in the manufacturer's specifications.
   d. The method in manufacturer's specifications used to confirm microbial inactivation and the test results.
   e. Any other operating parameters ~~as set forth~~ in the manufacturer's specifications for each treatment cycle.

4. Keep records of equipment maintenance for the duration of equipment use that include the date and result of all equipment calibration and maintenance.

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

F. A generator shall do all of the following:
~~1. Package the treated medical waste.~~
   ~~a. According to the waste collection agency's requirements;~~
   ~~b. Attach to the package or container a label, placard, or tag with the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection. The generator shall ensure that the label, placard, or tag is easily readable at a distance of 10 feet.~~
~~2. Upon request of the solid waste collection agency or municipal solid waste landfill, provide a certification that the treated medical waste meets the standards of R18-13-1415.~~
~~3. Make treatment records available for Departmental inspection upon request.~~
~~4. Dispose of the treated medical waste at a Departmental approved municipal solid waste landfill or, if the waste was prepared for recycling as required by R18-13-1416, dispose at a Department approved solid waste recycling facility.~~
1. Package the treated medical waste according to the waste collection agency's requirements;
2. Attach to the package or container a label, placard, or tag with the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection as a general solid waste. The generator shall ensure that the treated medical waste meets the standards of R18-13-1415.
3. Upon request of the solid waste collection agency or municipal solid waste landfill, provide a certification that the treated medical waste meets the standards of R18-13-1415.
4. Make treatment records available for Departmental inspection upon request.

~~**G.** Medical sharps shall be rendered incapable of being reused before packaging.~~

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

~~**H.** Encapsulation of regulated medical waste or medical sharps waste and subsequent disposal as solid waste is acceptable. if the agent used to solidify and encase the contents meets the treatment standards of R18-13-1415.~~

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

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

A. A generator of ~~regulated~~ biohazardous medical waste shall package the waste as ~~described~~ prescribed in R18-13-1407 before self-hauling or before setting the waste out for collection by a transporter.

B. A generator shall obtain a copy of the tracking document signed by the transporter signifying acceptance of the biohazardous medical waste. ~~from the transporter for each waste load accepted by the transporter. In addition,~~ A generator shall keep a copy of the tracking document for 1 year from the date of acceptance by the transporter. The tracking document shall contain all of the following information:
1. Name and address of the generator, transporter, and medical waste treatment, storage, transfer, or disposal facility, as applicable.
2. Quantity of ~~regulated~~ biohazardous medical waste collected by weight, volume, or number of containers.

...

4. Date the ~~regulated~~ biohazardous medical waste is collected.

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

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

R18-13-1407. Packaging ~~of Regulated Medical Waste~~

A. A generator who sets ~~regulated~~ biohazardous medical waste out for collection for off-site treatment or disposal shall package the ~~regulated~~ biohazardous medical waste in either of the following:

1. A red disposable plastic bag that is:
   ~~a. Of sufficient thickness to prevent breakage~~.
   ~~b. Sealed to prevent leakage of contents during storage, handling, or transport.~~
   ~~c. 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 which bears the universal biohazard symbol. The secondary container may be either disposable or reusable~~. ~~"Universal biohazard symbol" means a representation that conforms to the design shown in 29 C F R 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1997) and which is incorporated by reference in this rule. Copies of the incorporated material are available for inspection at the Department of Environmental Quality and the Office of the Secretary of State.~~
   a. Leak resistant,
   b. Impervious to moisture,
   c. Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling,
   d. Sealed to prevent leakage during transport, ~~and~~
   e. Puncture resistant for sharps, and
   ~~c.~~f. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and ~~which~~ bear~~s~~ the universal biohazard symbol. The secondary container may be either disposable or reusable. ~~"Universal biohazard symbol" means a representation that conforms to the design shown in 29 C F R 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1997) and which is incorporated by reference in this rule. Copies of the incorporated material are available for inspection at the Department of Environmental Quality and the Office of the Secretary of State.~~
2. A reusable container ~~or bag~~ that bears the universal biohazard symbol and that is:
   a. Leak-proof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water, and
   ~~b. Composed of disposable packaging and liners shall be managed as regulated medical waste and not reused,~~
   ~~c.~~b. Used for the storage or transport of ~~regulated~~ biohazardous medical waste ~~and designated for reuse once emptied, shall be decontaminated~~ and cleaned after each use unless the inner surfaces of the container have been protected ~~from contamination~~ by disposable liners, bags, or other devices removed with the waste. ~~"Decontamination"~~ "Cleaning" means agitation to remove visible ~~soil~~ particles combined with 1 of the following:
      ...
      ii. Exposure to an EPA-approved chemical disinfectant used under established protocols and regulations.
      iii. Any other ~~manner~~ method that the Department determines is acceptable, if the determination of acceptability is made in advance of the ~~decontamination.~~ cleaning.

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

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

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

R18-13-1408. Storage ~~of Regulated Medical Waste~~

A. A generator may place a container of ~~regulated~~ biohazardous medical waste alongside a container of solid waste if the ~~regulated~~ 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. Once biohazardous medical waste has been packaged for shipment off site, a generator shall provide a storage area for ~~the storage of regulated~~ biohazardous medical waste until the waste is collected and shall ~~meet~~ comply with both of the following requirements:

~~1. Secure the storage area by a door and lock if the storage area is located indoors or a fenced in area with a gate and lock if the storage area is located outdoors.~~

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

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

1. Keep putrescible ~~regulated~~ biohazardous medical waste unrefrigerated if it does not create a nuisance. ~~Putrescible~~ However, refrigerate at 40° F. or less putrescible ~~regulated~~ biohazardous medical waste ~~may be~~ kept ~~longer~~ more than 7 days ~~if it is refrigerated at 40° F. or less~~.
2. Store ~~regulated~~ biohazardous medical waste ~~for longer than 90 days only~~ for 90 days or less ~~if~~ 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 ~~described~~ prescribed in R18-13-1412.
3. Keep the storage area free of visible contamination.
4. Protect ~~regulated~~ biohazardous medical waste from contact with water, precipitation, wind, or animals. ~~The waste shall not provide a breeding place or a food source for insects or rodents.~~ A generator shall ensure that the waste does not provide a breeding place or a food source for insects or rodents.
5. Handle spills by re-packaging the ~~regulated~~ biohazardous medical waste, re-labeling the containers and ~~decontaminating~~ cleaning any soiled surface ~~as described in R18-13-1407(A)(2)(c).~~ as prescribed in R18-13-1407(A)(2)(b).
6. Notwithstanding ~~paragraph 1 of this subsection~~, subsection (C)(1), if odors become a problem, a generator shall minimize objectionable odors and the off-site migration of odors. ~~If a generator complies with (C)(1) through (C)(5) of this subsection and the facility is unable to control the odor, the Department may require waste removal after 3 days or waste refrigeration.~~If the Department determines that a generator has not acted or adequately addressed the problem, the Department shall require the waste to be removed or refrigerated at 40° F or less.

R18-13-1409. Transportation ~~of Regulated Medical Waste~~

A. A transporter shall register with the Department ~~registration~~ 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. Upon receiving all of the following information from a transporter, the Department shall issue the registration after assigning a registration number to the transporter:

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 ~~an~~ a written acknowledgment that this disclosure is not required.
5. Photocopies or other evidence of the issuance of a permit, license, or approval ~~where~~ if required by a local health department, environmental agency, or other governmental agency with jurisdiction. ~~as described in subsection (A).~~
6. A copy of the transportation management plan required in subsection (C).

C. A person who transports ~~regulated~~ 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 ~~to~~ of employees and the general public to ~~regulated~~ biohazardous medical waste throughout the process of collecting, transporting, and handling.
2. Emergency procedures used for handling spills or accidents.

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

E. A transporter who transports ~~regulated~~ biohazardous medical waste in a vehicle dedicated to the transportation of ~~regulated~~ biohazardous medical waste shall ensure that the cargo compartment can be secured to limit access to authorized persons at all times except during loading and unloading. In addition, the cargo compartment shall be constructed in compliance with ~~one~~1 of the following:

1. Have a fully enclosed, leak-proof cargo compartment consisting of a floor, sides, and a roof that are made of ~~an impervious material, or material that is otherwise sealed~~ 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 ~~an impervious and non-porous material.~~ a non-porous material impervious to biohazardous medical waste.
3. Tow a fully enclosed leak-proof trailer made of ~~an impervious and non-porous material.~~a non-porous material impervious to biohazardous medical waste.

F. A person who transports ~~regulated~~ biohazardous medical waste in a vehicle not dedicated to the transportation of ~~regulated~~ biohazardous medical waste, but that is used longer than 30 consecutive days ~~in commerce~~, shall comply with the following:
1. ~~Subsection~~Subsections (A) and ~~(E)~~ (C) through (G).
2. ~~Decontaminate~~ Clean the vehicle ~~before it is used again.~~ as prescribed in R18-13-1407(A)(2)(b) before it is used for another purpose.

G. A person who transports ~~regulated~~ biohazardous medical waste shall comply with all of the following:
1. Accept only ~~regulated~~ biohazardous medical waste packaged as ~~described~~ prescribed in R18-13-1407.
2. Accept ~~only regulated~~ biohazardous medical waste only after providing the generator with a signed ~~accompanied by a~~ tracking form as ~~described~~ prescribed in R18-13-1406(~~E~~)(B), and keep a copy of the tracking document for 1 year.
3. Deliver ~~regulated~~ biohazardous medical waste to a Department-approved ~~regulated~~ 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.
4. Not hold ~~regulated~~ biohazardous medical waste longer than 96 hours in a refrigerated vehicle unless the vehicle is parked at a Department-approved facility.
5. Not unload, reload, or transfer the ~~regulated~~ 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 ~~coupled and uncoupled~~ uncoupled and coupled to another cargo vehicle or truck trailer as long as the ~~regulated~~ biohazardous medical waste is not removed from the cargo compartment.
6. ~~Securely close all discharge openings during operation of the vehicle.~~
7. ~~Lock the cargo compartment at all times when regulated medical waste is present except during loading or unloading~~.

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

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

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

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

R18-13-1411. ~~Medical Waste~~ Storage and Transfer Facilities; Design and ~~Operational Requirements.~~ Operation

An operator of a storage facility or transfer facility shall be in compliance with all of the following design and operation requirements:
1. ~~The facility shall be designed~~ Design the facility so that ~~regulated~~ biohazardous medical waste is always handled and stored separately from other types of solid waste if accepted at the facility.
2. Display prominently the universal biohazard symbol ~~and post warning signs worded~~ as ~~described~~ prescribed in R18-13-1401.
3. Construct the storage area from smooth, easily cleanable non-porous materials~~s~~ that ~~are~~ is impervious to liquids and resistant to corrosion by disinfecting agents and hot water.
4. Protect ~~regulated~~ biohazardous medical waste from contact with water, precipitation, wind, or animals.
5. Specify in the application for facility plan approval the maximum storage time that ~~regulated~~ biohazardous medical waste ~~shall~~ will remain at the facility. If the ~~regulated~~ biohazardous medical waste will be stored for ~~longer~~ more than 24 hours, the operator shall equip the facility ~~shall be equipped~~ with a refrigerator to refrigerate the ~~regulated~~ biohazardous medical waste. The operator of the facility shall maintain the temperature in the refrigerator at 40° F. or ~~lower.~~ less.
6. Accept ~~regulated~~ biohazardous medical waste only if it is accompanied by the tracking form. The operator shall sign the tracking form and keep a copy of the acceptance documentation for ~~a period of one~~1 year;

7. Accept ~~regulated~~ biohazardous medical waste if it is packaged as described in R18-13-1407. If a ~~regulated~~ biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a transfer facility operator shall do ~~one~~ 1 of the following:
   a. Reject the waste and return it ~~to the generator~~ to the transporter.
   b. Accept the waste and immediately repackage it as ~~described~~ prescribed in R18-13-1407(A).
8. ~~Decontaminate~~ Clean the storage area daily as ~~described~~ prescribed in R18-13-1407(A)(2)~~(c)~~. ~~on a regular basis and after any spills.~~

R18-13-1412. ~~Medical Waste~~ Treatment Facilities; Design and ~~Operational Requirements~~ Operation

A. An operator who applies for facility plan approval shall ~~demonstrate compliance~~ comply with all of the following:
1. ~~Documentation~~ Submit to the Department the following documentation: ~~for all of the following equipment specifications:~~
   a. Equipment specifications that identify the proper type of medical waste to be treated in the equipment and any design or equipment restrictions.
   b. Manufacturer's specifications and operating procedures for the equipment that describe the type and volume of waste to be treated, monitoring data of the treatment process, and calibration and testing of the equipment, ~~that detail~~ providing specific details about the capability of the equipment to achieve the treatment standards ~~described~~ prescribed in R18-13-1415.
   c. Instructions for equipment maintenance, testing, and calibration that ensure the equipment achieves the treatment standards ~~described~~ prescribed in R18-13-1415.
   d. Training manual for the equipment.
   e. Written certification from the manufacturer stating that the equipment, when operated properly, is capable of achieving the treatment standards ~~described~~ prescribed in R18-13-1415.
2. Submit to the Department and have readily available at the facility, an operations procedures 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 procedures manual shall include all of the following:
   a. Provisions for treating ~~regulated~~ biohazardous medical waste within 24 hours of receipt or refrigerating immediately at 40° F. or ~~lower~~ less upon determination that treatment or disposal will not occur within 24 hours.
   b. A contingency plan if the treatment equipment is out of service for an extended period of time. The plan shall address the manner and length of time for storage of the waste. ~~The length of time the regulated~~ An operator shall not store biohazardous medical waste ~~can remain in storage shall not exceed~~ more than 90 days. ~~and~~ The plan shall be based on the capacity of the treatment equipment to treat ~~the~~ all waste ~~backlog of stored waste~~ at the facility, ~~together with the ongoing operations~~ including any backlog of stored waste and any new waste intake. If the 90-day time-frame will be exceeded, the operator shall either stop accepting waste until the backlog is treated, or contract with another treatment facility ~~to assist in~~ for treating the waste.
   c. Procedures for handling hazardous chemicals, radioactive waste, and chemotherapy waste. The plan shall provide for scanning ~~regulated~~ biohazardous medical waste with a Geiger counter and handling waste that measures above background level in ~~compliance~~ a manner that complies with state and federal law.
   ~~d. Procedures for cleaning and decontaminating the processing area of waste at the end of every working day unless the facility is approved to process waste on a 24 hour basis. If the facility is approved to process waste on a 24 hour basis, the processing area shall be cleared of waste and decontaminated after every 24 hours of operation.~~
3. ~~Accept~~ Have on hand written procedures stating that ~~regulated~~ biohazardous medical waste is to be accepted from a transporter only if the waste is accompanied by a tracking form, and ~~comply~~ written procedures that require compliance with both of the following:
   a. ~~Sign~~ The treater or the treater's authorized agent shall sign the tracking document and keep a copy of the acceptance documentation for ~~a period of~~ 1 year.
   b. If a ~~regulated~~ biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do ~~one~~1 of the following:
      i. Reject the waste and return it to the ~~generator~~ 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 ~~regulated~~ 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 ~~shall~~ either ~~have~~ has a curb of sufficient height to contain spills or ~~shall slope~~ slopes to a drain that connects to an approved sanitary sewage system, ~~approved~~ septic tank system, or collection device.
5. Store ~~regulated~~ biohazardous medical waste as required in R18-13-1408(~~E~~).

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. ~~Perform a waste determination of~~ Determine whether the ash ~~to determination whether the ash~~ is hazardous waste as ~~described in~~ 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.
~~7.~~11. Keep records of equipment maintenance and operational performance levels for 3 years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall ~~include~~ indicate the duration of time for each treatment cycle ~~as follows~~ 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 ~~as set forth~~ 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.

...

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

...

B. As required by A.R.S. § 49-762.06, a treatment facility operator who has identified ~~the~~ a change ~~as described in~~ under subsection (A) shall comply with ~~one~~1 of the following:
1. For a Type ~~1~~ I change, make the change without notice to, or approval by the Department.
2. For a Type ~~2~~ II change, before making any change, provide written notification that describes the change to the Department. The addition of refrigeration units only for compliance with this Article is a Type ~~2~~ II change for which no Departmental approval is required.
3. For a Type ~~3~~ III or Type ~~4~~ IV change, submit an amended plan to the Department for approval before making any change. Departmental approval is required prior to making any change.

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

A. ...
7. Written documentation demonstrating ~~that demonstrates~~ that the alternative medical waste treatment method is capable of compliance with the treatment standards in this Article for the type of waste treated. ~~The demonstration shall be made by~~ The manufacturer shall employ a laboratory independent of any oversight activities by the manufacturer to provide this analysis.
8. The manufacturer's equipment specifications for the alternative medical waste treatment method being registered, including all of the following:
   a. Unit model number, or serial number.
   b. Equipment specifications that identify the proper type of ~~regulated~~ biohazardous medical waste to be treated by the equipment and any design or equipment restrictions.

c. Operating procedures for the equipment that ensure the equipment complies with the treatment standards ~~described~~ prescribed in this Article for the type of waste treated.
d. Instructions for equipment maintenance, testing, and calibration that ensure the equipment complies with the treatment standards ~~described~~ prescribed in this Article for the type of waste treated.

9. Written documentation of registration where required by A R.S. § 3-351.

B. The Department shall make a determination whether ~~or not~~ to approve the registration application. If the Department approves the application, it shall issue to the applicant a certification of registration containing an alternative medical waste treatment method registration number ~~to the applicant.~~ Only an alternative technology method with a valid Department issued registration number ~~shall qualify as meeting~~ meets the requirements of this Article.

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

~~**A.** Regulated medical waste treated by 1 of the following methods is treated medical waste:~~
~~1. Incineration, that reduces the incinerated medical waste, excluding metallic items, into carbonized or mineralized ash.~~
~~2. Steam sterilization or other sterilization, that achieves complete elimination or destruction of all forms of microbial life.~~
~~3. An alternative medical waste treatment method that meets the treatment standards set forth in subsection (E).~~

~~**B.** A person who generates the following regulated medical waste categories shall meet all the following additional requirements:~~
~~1. Ensure that cultures and stocks are incinerated, steam sterilized or treated by an alternative medical waste treatment method that achieves sterilization.~~
~~2. Ensure that chemotherapy waste is incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.~~
~~3. If grinding is used in combination with another treatment method described in this Article, ensure that it is conducted in a closed system to prevent exposure to humans and the environment. If grinding is used for medical sharps, this grinding shall render the medical sharps incapable of being reused.~~
~~4. Handle medical sharps according to both of the following:~~
~~a. Render incapable of being reused.~~
~~b. Ensure treatment by one of the following:~~
~~i. Sending to a Departmental approved medical waste treatment facility.~~
~~ii. Packaging as instructed by the transporter and send them to a treatment facility via a mail back system. An Arizona treatment facility shall render medical sharps incapable of being reused.~~
~~iii. Using an encapsulation agent that meets the standards of subsection (D) before disposal in a landfill.~~

~~**C.** A person shall not used compaction as a treatment method for regulated medical waste.~~

~~**D.**~~**A.** A treater using an alternative treatment technology shall ensure that treatment achieves either of the following treatment standards:

~~1. Inactivation is required to be demonstrated for vegetative bacteria, fungi, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log_{10} reduction or greater.~~
1. A 6 $\log_{10}$ inactivation in the concentration of vegetative microorganisms
~~2. Inactivation is required to be demonstrated of B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater.~~
2. A 4 $\log_{10}$ inactivation in the concentration of Bacillus stearothermophilus or Bacillus subtilis as is appropriate to the technology.

~~**E.** A treater utilizing an alternative treatment method shall use one or more of the following representative biological indicators to demonstrate treatment efficacy:~~
~~1. One or more of the following representative microorganisms from each microbial group shall be used to determine if microbial inactivation requirements are met:~~
~~a. Vegetative bacteria:~~
~~i. Staphylococcus aureus (ATCC 6538),~~
~~ii. Pseudomonas aeruginosa (ATCC 15442).~~
~~b. Fungi:~~
~~i. Candida albicans (ATCC 18804),~~
~~ii. Penicillium chrysogenum (ATCC 24791), or~~
~~iii. Aspergillus niger.~~
~~c.~~ Viruses:
~~i. MS-2 Bacteriophage (ATCC 15597-B1).~~
d. ~~Parasites:~~
~~i. Cryptosporidium spp. oocysts.~~
~~e. Mycobacteria:~~
~~i. Mycobacterium terrae,~~
~~ii. Mycobacterium phlei, or~~

~~iii. Mycobacterium bovis (BOG) (ATCC 35743).~~

~~2. Spores from one of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems:~~

~~a. B. stearothermophilus (ATCC 7953),~~

~~b. B. subtilis (ATCC 19659).~~

B. A treater utilizing an alternative treatment method shall conduct efficacy studies to demonstrate that the treatment mechanisms are capable of achieving the standards in subsection (A) through either of the following:

1. Mycobacterial species used as indicators of vegetative microorganisms:
   a. Mycobacterium phlei, or
   b. Mycobacterium bovis (BOG) (ATCC 35743)
2. Spore suspensions of 1 of the following 2 bacterial species, as appropriate to the technology, used as biological indicators in efficacy tests of thermal, chemical, and irradiation treatment systems. Studies shall demonstrate a 4 $\log_{10}$ reduction in the concentration of viable spores, through the use of an initial inoculum suspension of 5 $\log_{10}$ or greater of:
   a. Bacillus stearothermophilus (ATCC 7953), or
   b. Bacillus subtilis (ATCC 19659).

[Subsection (C) is shown below. It is included here because as explained in section #11, "changes made throughout the text," ADEQ was advised that the numerical values and calculations were wrongly expressed as superscript and should be expressed as subscripts. Due to the size of the font, underlining and strike out was not feasible.]

~~D.~~**C.** A treater utilizing an alternative treatment method shall quantify microbial inactivation as follows:

1. Microbial inactivation, or "kill" efficacy is equated to "Log_{10} Kill" that is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment. This definition is ~~equated~~ stated as:
   $Log_{10}Kill = Log_{10}(cfu/g\ "I") - Log_{10}(cfu/g\ "R")$
   where:
   $Log_{10}Kill$ is equivalent to the term Log_{10} reduction,
   "I" is the number of viable test microorganisms introduced into the treatment unit,
   "R" is the number of viable test microorganisms recovered from the treatment unit, and
   "cfu/g" are colony forming units per gram of waste solids.
   ...
3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator, quantitative measurement of microbial inactivation requires a 2-step approach: Step 1 "Control" and Step 2 "Test". The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.
   a. Step 1:
   ...
      v. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction, either a 6 Log_{10} reduction for vegetative microorganisms or a 4 Log_{10} reduction for bacterial spores. This can be defined by the following equation:
      $Log_{10}RC = Log_{10}IC - Log_{10}NR$
      or
      $Log_{10}NR = Log_{10}IC - Log_{10}RC$
      where:
      $Log_{10}RC$ is greater than 6 for vegetative microorganisms and greater than 4 for bacterial spores and where:
      $Log_{10}RC$ is the number of viable ~~"Control"~~ "control" microorganisms in colony forming units per gram of waste solids recovered in the non-treated processed waste residue;
      $Log_{10}IC$ is the number of viable ~~"Control"~~ "control" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit;
      $Log_{10}NR$ is the number of ~~"Control"~~ "control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated, processed waste residue. $Log_{10}NR$ represents an accountability factor for microbial loss.
   b. Step 2:
   ...
      v. From data collected from Step 1 and Step 2, the level of microbial inactivation, "Log $_{10}$ Kill", is calculated by employing the following equation:
      $Log_{10}Kill = Log_{10}IT - Log_{10}NR - Log_{10}RT$

where:

Log_{10}Kill is equivalent to the term Log_{10} reduction;

Log_{10}IT is the number of viable "Test" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit. $Log_{10}IT = Log_{10}IC$;

Log_{10}NR is the number of "Control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated processed waste residue;

Log_{10}RT is the number of viable "Test" microorganisms in colony forming units per gram of waste solids recovered in treated, processed waste residue.

~~**D.** Any methodology employed to determine treatment efficacy of the technology shall assure required microbial inactivation and shall assure that the protocols are congruent with the treatment method. Acceptable demonstration of compliance is required to be provided by an independent testing laboratory.~~

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

R18-13-1416. Recycled Materials

A. Once a generator places ~~regulated~~ biohazardous medical waste in a red bag as required in ~~R18-13-1409,~~ R18-13-1407, ~~no one~~ a person shall not remove any of the ~~regulated~~ biohazardous medical waste from the bag until the ~~regulated~~ biohazardous medical waste has been treated as required in R18-13-1415.

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

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

R18-13-1417. Disposal Facilities; ~~Operational Requirements~~ Operation

An operator of a municipal solid waste landfill that accepts untreated ~~regulated~~ biohazardous medical waste shall ~~demonstrate compliance with all of the following in its facility plan:~~ comply with all the following design and operational requirements:

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

R18-13-1418. Discarded Drugs

A. A generator of discarded drugs not returned to the manufacturer shall destroy the drugs on site 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

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.

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.

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 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 secondary inner container that is then placed inside an 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 waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
3. Experimental or research animal waste shall be handled as follows:
   a. Autoclave bedding on site or package as described in R18-13-1407 for off- site treatment or land filling.
   b. Incinerate animal carcasses on site, or if taken off site for treatment, comply with 1 of the following requirements:
      i. Package the waste in a leakproof, covered container, label the contents and send to an incinerator or a Department-approved landfill, or
      ii. If treated by a method other than incineration, pre-process by grinding, then treat by a method that achieves the standards of R18-13-1415(A).

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

11. A summary of the principal comments and the agency response to them.

GENERAL COMMENTS

(Please note that this summary sometimes presents 2 different Department responses regarding the same rule or issue. The 1st is the initial response submitted to GRRC. The 2nd is the final response in light of comments received by GRRC staff.)

The preliminary summary of the economic, small business and consumer impact

ISSUE: In describing conclusions which ADEQ has reached regarding this rule, in the 3rd conclusion, the statement that "public health benefits should accrue..." is incorrect. The spread of communicable disease from "biohazardous medical waste" outside of a facility has never been documented. Any such potential is only theoretical. We believe such a benefit to be unlikely.

ANALYSIS: ADEQ agrees that there is a difference of scientific opinion as to the likelihood of disease transmission from biohazardous medical waste. This commenter failed to provide a more detailed analysis, and without being given specific alternatives ADEQ continues to rely on its own research as described in the economic, small business and consumer impact statement (EIS).

RESPONSE: No change to the rule.

ISSUE: Several commenters stated that the rule benefits are overstated, that the economic impact statement fails to demonstrate that the probable benefits of the rule outweigh the probable costs. Several commenters stated that there is no expected reduction in infection or disease as a result of these rules, since none have ever been attributed to biohazardous medical waste.

ANALYSIS: The preliminary EIS has been revised and is included in section 9. None of these commenters provided more detailed analysis, and without specific alternatives, ADEQ continues to rely on its own research as described in the EIS.

RESPONSE: No change to the rule.

ISSUE: The costs are understated, and ADEQ assumes that the only costs imposed by the rule will be costs incurred by gener-

ators who do not currently treat their wastes.

ANALYSIS: The EIS contains an estimate of costs based upon the results reported to ADEQ in its survey and has not based costs upon assumptions. ADEQ's research shows that the rule by and large codifies current behavior.

RESPONSE: No change to the rule.

ISSUE: The rule as proposed does not comply with the requirement in A.R.S. § 49-1035 to reduce the impacts on small businesses. Allowing Level III treatment for all biohazardous wastes, including cultures and stocks, would reduce the impact of the rule on small businesses by allowing continued reliance on alternative treatment technologies.

ANALYSIS: ADEQ recognizes that authorities in the field, such as the "Biosafety in Microbiological and Biomedical Laboratories" (3rd edition, Center for Disease Control) and the Arizona Department of Health Services recommend autoclaving cultures and stocks. Indeed, the Arizona Hospital and Healthcare Association advises ADEQ in a letter dated March 18, 1999, that most of its members sterilize cultures and stocks on or off-site with 1 and perhaps 2 members who do not. ADEQ has responded to the separate issue of sterilizing cultures and stocks and now allows Level III (high disinfection) for cultures and stocks treated by an alternative treatment method. Given that authorities in this field recommend autoclaving, and the fact that the current industry practice is to autoclave cultures and stocks on-site, ADEQ does not believe that the rule as proposed fails to meet A.R.S. § 49-1035.

RESPONSE: The rule now reads:
Ensure that cultures and stocks are incinerated, autoclaved, or treated by an alternative medical waste treatment method that meets the treatment standards set forth in R18-13-1415(A).

ISSUE: In the preliminary summary of the impact of this rule (under subsection (5), Rule Benefits), ADEQ acknowledges public fear of "imagined" risks. Attempting to qualm irrational fear by imposing unnecessary treatment standards cannot be supported. To do so would officially reinforce mis-perceptions at the expense of medical care provision, and make educational work more difficult. It is inappropriate in the extreme for a government agency to impose standards it knows to be unjustified.

ANALYSIS: ADEQ recognizes that this "imagined" risk is very real to landfill workers and others who come into contact with the biohazardous medical waste stream. People act on their perception of risk all the time, as evidenced in the current practice of many landfills refusing to accept untreated biohazardous medical waste. As a regulatory agency, ADEQ must be responsive to affected stakeholders who communicate and act on their perceptions of risk, whether "real" or "imagined."

RESPONSE: No change to the rule.
Licensing time-frames.

ISSUE: There is no reason why the Department should wait to undertake a separate rulemaking to establish licensing time-framesfor the new licenses required by this rule. For newly created licenses it would be far more efficient to establish the licensing requirements and time-frames in the same rulemaking. The concern is that Department delays in approving registrations for new treatment technologies will create artificial market barriers for more cost-effective treatment options. We agree with ADEQ's suggestion that 45 days would be an adequate review period for these registrations and asks that this time limitation be incorporated in the final rule.

ANALYSIS: The licensing time-frames rule (LTF) is required by A.R.S. Title 41, Chapter 6, Article 7.1 and requires all state agencies to adopt licensing time-frames for every license, approval, registration, charter, or similar form of permission they issue. Because the licensing time-frames apply to ADEQ licensing decisions in almost all of its programs in addition to just medical waste, the Department is using a unitary rule that applies common definitions and provisions to all licenses subject to Article 7.1 licensing time-frames. To this end, ADEQ proposed its licensing time-frames rule in the *Arizona Administrative Register* at p.3089 (October 23, 1998) and expects that rule to be effective soon. ADEQ has already announced that all new licensing activity subject to Article 7.1 and identified after October 1998 will be included in the next scheduled annual LTF amendatory rulemaking. As LTF is contained in Chapter 1 of the *Arizona Administrative Code*, Title 18, license categories for medical waste cannot be added to today's rule as this medical waste rule is located in Chapter 13, and the secretary of state prohibits rulemaking across chapters.

The statutory time-frames remain as currently required in statute for all solid waste facility plans, including medical waste facility plans, and are found at A.R.S. § 49-762.04. ADEQ expects the same times and category breakdowns as shown in the proposed licensing time-frames rule on Table 13 ("Special Waste Licenses") for categories 6-15 except that only "standard" categories will be shown and there will be no "complex" categories shown. The proposed licensing time-frames rule is found

in the October 23, 1998, *Arizona Administrative Register* at page 3089.

RESPONSE: No change to the rule.

ISSUE: "In the background for the proposed rules, ADEQ points with pride to the "public participation" that was involved. I have personally participated in the public comment, including the described roundtable meetings, beginning in 1994. While it is fine to solicit input from as many sources as possible, I have been shocked by the prominent voice afforded industry representatives who stand to benefit handsomely from these rules. At times, both in number and assertiveness, such representatives overwhelmed those representing legitimate scientific and public health concerns. The agency should not consider seriously the opinions, unless supported by scientific facts, of companies whose financial motivation would compel them to advocate for as much treatment and as much regulation as possible. The agency cannot attempt to "balance" the interests of such corporations against scientific fact and the interest of public health.
In summary, ADEQ's responsibility is to regulate when necessary to protect the public health or environment. The agency should not issue rules about nonexistent risks in an attempt fool a fearful public into believing that they are being "protected." The agency should not issue unnecessary rules for the sake of "compromise" between an industry's financial motivation on 1 side and scientific reality on the other. The agency should only base its rules upon scientific fact and demonstrated risk. The bulk of these proposed rules are not supportable by fact."

ANALYSIS: The ADEQ view of public participation in the rulemaking process differs from this commenter's experience. ADEQ's view is that regulatory compliance is best achieved by obtaining the consent of the governed, however grudgingly that consent may be obtained. ADEQ has based its public participation efforts on these principles: the public should have a say in decisions about actions that affect their lives; ADEQ's public participation includes the promise that the public's contribution will influence the decision; the public participation process communicates the interests and meets the process needs of participants; and the public participation process actively seeks out and facilitates the involvement of those potentially affected. Another guiding principle of the public participation process in this rulemaking is an effort to find an approach for handling biohazardous medical waste that recognizes the reality and perceptions that those coming into contact with this waste stream can live with. ADEQ recognizes that the views of the "experts" are not necessarily shared or accepted by others, and further recognizes that financial motivation is not a reason for limiting stakeholder involvement.

RESPONSE: No change to the rule.

ISSUE: These rules need to begin with a rational definition of regulated waste, based on actual risk from the product rather than on its origin in a medical versus a nonmedical setting. The justification for regulatory action should be existence of a real (not a calculated or hypothetical) danger to someone, not the lack of a piece of paper, and the degree of danger should be greater than some threshold.

ANALYSIS: In 1993, ADEQ consulted with the Arizona Department of Health Services in the original definition of biohazardous medical waste as required by statute. Subsequent revisions to the definition were made in response to public comments. These most recent revisions to the definition reflect input suggested by the Arizona Department of Health Services.

RESPONSE: No change to the rule.

ISSUE: The high disinfection treatment level is unjustified. Specific wastes which pose risk should be identified for incineration or sterilization, with all other biohazardous medical waste handled as solid waste. Those specified wastes are stocks and cultures, for which a 6 log reduction of vegetative bacteria and 4 log reduction of Bacillus spores
should be used as it is the equivalent of "high level disinfection," except for Bacillus anthracis (anthrax) which should be sterilized. For human pathologic wastes prion-related diseases (such as Kuru and Creutzfeldt-Jakob Disease) should be identified as requiring incineration. In addition, research animal waste containing anthrax, Q fever and prion-related diseases (such as scrapie, TSE and BSE) should be identified as requiring incineration.

ANALYSIS: ADEQ has incorporated into the rule the ADHS definitions with some changes. These changes to the definition are indicated below in the specific rule sections. However, ADEQ retains its original position that biohazardous medical waste in general should be treated to a high disinfection level. ADEQ retains this position, which is consistent with the recommendations of the revised "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" (STAATT II). STAATT II represents a group of state and territorial regulators which have recommended treatment levels in an effort to achieve consistent state wide standards and efficacy testing for those standards.

RESPONSE: Rule sections have been changed as specified below.

ISSUE: The following statement is in direct conflict with the traditional policy under the Resource Conservation and Recovery Act: "Once a hauler accepts regulated medical waste from the generator, the waste becomes the property of the hauler."

ANALYSIS: ADEQ has taken this statement out of the preamble and made related rule changes in R18-13-1403. See discussion below under R18-13-1403(C)(2).

RESPONSE: Change made to the preamble.

Changes made throughout the text. Several changes were made to the rule text as a whole and are described here for the sake of brevity. The rule text has been changed to provide consistent reference to "Department-approved" facilities. For this same purpose, consistent references to the treatment standards have been added. As is explained below, the term "regulated medical waste" has been changed to "biohazardous medical waste" throughout the text. The term "steam sterilization" has been replaced throughout the text by the term "autoclaving" to reflect present use of autoclaving in the medical community. The term "decontaminated" has been replaced throughout the text by the term "cleaned" because ADHS suggested that the word "decontaminate" was used in the rule text inappropriately.
In R18-13-1404, the Arabic numbers have been replaced with roman numerals to reflect the fact that facility changes described in A.R.S. 49-762 are expressed in roman numerals. The rule text also has been changed to reflect minor grammatical changes, or minor clarification changes, such as the insertion of a noun in the place of a pronoun.
In R18-13-1415(C), ADEQ was advised that the numerical values and calculations were wrongly expressed as superscript and should be expressed as subscripts. That correction has been made.
Minor grammatical corrections have been made, such as the addition of commas and adjustments made to hyphenated words.

RULE TEXT

The following definitions are numbered as they appear in the final rule.
R18-13-1401(2) "Alternative treatment technology"

The reference to the treatment standards of R18-13-1415 has been added to clarify that alternative treatment technology must meet the treatment standards. The rule now reads:

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

R18-13-1401(3) "Approved medical waste facility plan"

This has been amended to show the proper statutory citation.

R18-13-1401(4) "Autoclaving"

ISSUE: The definition of autoclaving is not clear. It is better defined as using a combination of heat, steam, pressure and time to achieve sterile conditions.

ANALYSIS: ADEQ agrees.

RESPONSE: R18-13-1401(4) now reads:

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

R18-13-1401(5) "Biohazardous medical waste"

R18-1401(5), which describes of the categories of biohazardous medical waste, has undergone extensive revision as a result of comment letters and continued discussions between ADEQ and ADHS. The final rule language represents the ADHS suggestions with the exceptions and revisions discussed below. With regard to research animal waste, ADEQ chose to regulate the general category as opposed to specific wastes within the category. ADEQ chose this simplified approach, rather than requiring specific identification of disease classifications to determine if the waste was regulated. With regard to isolation waste, in its comment letter ADHS recommended that isolation waste not be regulated, unless it falls into another class of waste otherwise defined in these rules, such as free flowing blood, because otherwise it should pose no special hazard, and should be disposed of as any other hospital generated waste. ADEQ chose to follow the suggestion in the comment letter and drop the category entirely. Finally, with respect to cultures and stocks, the identification of "industrial laboratories" as a source of cul-

tures and stocks was removed, because ADEQ believes these facilities do not exist in Arizona. Below is printed the ADHS suggestions for the definition of medical waste, followed by specific discussion of comment letters.

ARIZONA DEPARTMENT OF HEALTH SERVICES
BUREAU OF EPIDEMIOLOGY AND DISEASE CONTROL SERVICES

Medical waste is defined as:

a. Cultures and stocks: Discarded cultures and stocks of human and animal infectious agents and associated microbiologicals shall be considered medical waste. This category includes human and animal cell cultures from pathology, medical microbiology and other clinical laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologics; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures of infectious agents.

b. Pathologic wastes: Discarded pathologic wastes (for example, organs and body parts) removed during surgery or autopsy.

c. Blood and blood products: Discarded products and materials containing free-flowing blood or free-flowing blood components.

d. Sharps: Discarded sharps used in animal or human patient care, medical research, or industrial laboratories. This includes hypodermic needles; syringes; pipettes; scalpel blades; blood vials; needles attached to tubing; broken and unbroken glassware in contact with infectious agents, and slides and coverslips.

e. Animal waste: Discarded material originating from animals inoculated with highly communicable diseases (Classification 4 by the Centers for Disease Control and Prevention (CDC) in "Biosafety in the Microbiologic and Biomedical Laboratory, 1993") during research, production of biologicals, or pharmaceutical testing. Examples are carcasses and body parts of animals known to have been infected or in contact with highly communicable infectious agents.

f. Selected precaution waste: Discarded waste material contaminated with excretions, exudates, and secretions from patients with highly communicable diseases (Classification 4 by the Centers for Disease Control and Prevention (CDC) in "Biosafety in the Microbiologic and Biomedical Laboratory, 1993") treated with special precautions.

ISSUE: Several commenters suggested the defined term "regulated medical waste" is unnecessary and confusing and should be deleted from this proposal. This section in effect defines "regulated medical waste" to mean the same thing as "biohazardous medical waste" contradicts the later definition, which includes both biohazardous waste and discarded drugs.

ANALYSIS: ADEQ agrees.

RESPONSE: The term "regulated medical waste" is deleted from the rule text and the term "biohazardous medical waste" is used instead. In addition, the title of the rule is changed to "Biohazardous Medical Waste and Discarded Drugs" to clarify that discarded drugs are not considered biohazardous medical waste and therefore not subject to treatment standards. Finally, a separate section "Discarded Drugs" has been added.

R18-13-1401(5)

ISSUE: The words "that is likely to transmit etiologic agent" is vague and may be difficult to interpret. Better language might be "that has been demonstrated to transmit an etiologic agent..."

ANALYSIS: ADEQ agrees.

RESPONSE: The rule text was initially changed as follows:

"Biohazardous medical waste" means that component of medical waste as defined in A.R.S. § 49-701 that has been demonstrated to transmit etiologic agent and is composed of 1 or more of the following:

R18-13-1401(5)(a)

ISSUE: The definition of cultures and stocks is unclear and open to misinterpretation.

ANALYSIS: ADEQ initially adopted the ADHS suggested definition.

RESPONSE: This definition was changed to:

Cultures and stocks: Discarded cultures and stocks of human and animal infectious agents and associated micro biologicals shall be considered biohazardous medical waste. This category includes human and animal cell cultures from pathology, medical microbiology and other clinical laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologics; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures of infectious agents.

R18-13-1401(5)(b)

ISSUE: For clarification, "specimens of body fluids" should be changed to "free flowing body fluids..."

ANALYSIS: ADEQ initially adopted the ADHS suggested definition.

RESPONSE: The definition was changed to:
Human blood and blood products: Discarded products and materials containing free-flowing blood or free-flowing blood components.

R18-13-1401(5)(c)

ISSUE: The definition of pathological wastes should be simplified. In addition, prion-related diseases (such as Kuru and Creutzfeldt-Jakob Disease) should be identified as requiring incineration.

ANALYSIS: ADEQ agrees that the definition should be simplified. However, ADEQ does not agree that specific diseases should be identified as requiring incineration. To identify exceptions within the categories for special handling makes compliance more difficult and complex.

RESPONSE: The definition has been changed to:
Human pathologic wastes: Discarded organs and body parts removed during surgery. Human pathologic wastes do not include the head or spinal column.

R18-13-1401(5)(d)

ISSUE: The use of the word "treatment" may be misinterpreted in this context because of the treatment definition in R18-13-1401(44). "Patient care" seems an adequate substitute. In addition, 1 commenter stated the words "device having acute rigid corners, edges or protuberances" was unnecessary.
Another commenter stated that it is irrational to treat unused medical sharps in the same manner as waste that poses an infectious hazard. Any sharp object in the garbage can cause injury and also infection.

ANALYSIS: ADEQ has adopted the ADHS suggested definition.

RESPONSE: The definition has been changed to:
Medical sharps: Discarded sharps used in animal or human patient care, medical research, or industrial laboratories. This includes hypodermic needles; syringes; pipettes; scalpel blades; blood vials; needles attached to tubing; broken and unbroken glassware and slides and coverslips.

R18-13-1401(5)(e)

ISSUE: It is difficult to justify the treatment of research animal wastes, while non research animals such as cattle, diary cows, pigs and poultry harbor and excrete literally tons of salmonellae, campylobacteriae, cryptosporidia, cyclospora and Escherichia coli O157:H7. These wastes remain untreated despite being the documented source of many outbreaks of disease. The same commenter suggested delineating anthrax, Q fever and prion-related diseases (such as scrapie, TSE and BSE) as requiring incineration.

ANALYSIS: ADEQ has revised the definition to regulate the class of animals that have been in contact with infectious agents. However, ADEQ requires that bedding is autoclaved on site or properly packaged for off site treatment or landfilling. Animal carcasses either incinerated on site, or if taken off site for treatment shall be properly packaged or pre-processed. Specific handling for research animal waste is found in R18-13-1420.

RESPONSE: The definition has been changed to:
Research animal wastes: Animal carcasses, body parts, and bedding of animals that have been infected with agents which pro-

duce, or may produce, human infection.

R18-13-1401(5)(f)
ISSUE: Some commenters were concerned that, as proposed, the definition was overly broad. One comment stated that not all wastes generated in a patient care environment in which special precautions have been implemented constitute a separate category of medical wastes. If waste generated in these settings do not fall into another class of waste otherwise defined in these rules, such as free flowing blood, then it should pose no special hazard, and should be disposed of as any other hospital generated waste.

With regard to the definition of isolation waste, several commenters stated that the phrase "highly communicable diseases" is a vague phrase, and does not always fit diseases for which various levels of precautions are implemented. Use of the term "Class IV diseases" was suggested, as this is a specific term used by the Centers for Disease Control and Prevention (CDC) to describe agents which require the most careful level of handling in a laboratory setting, due to infectiousness and/or virulence. One commenter pointed out that appropriate precautions should be taken depending upon the mode of transmission of various diseases, because not all diseases are spread by objects contaminated by the infected person.

ANALYSIS: ADEQ agrees that if waste generated in these settings do not fall into another class of waste otherwise defined in these rules, such as free flowing blood, then it should pose no special hazard, and should be disposed of as any other hospital generated waste. Therefore, the category of "isolation waste" has been deleted.

RESPONSE: This definition has been deleted.
The following changes were made to R18-13-1401(5) as a result of GRRC staff review:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
"Biohazardous medical waste" ~~means that component of medical waste as defined in A.R.S. § 49-701 that has been demonstrated to transmit etiologic agents and~~ is composed of 1 or more of the following:

a. ~~Cultures and stocks:~~ ~~Discarded cultures and stocks of human and animal infectious agents and associated microbiologicals shall be considered biohazardous medical waste. This category includes human and animal cell cultures from pathology, medical microbiology and other clinical laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologics; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures of infectious agents~~.
   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.
c. Human pathologic wastes: Discarded organs and body parts removed during surgery. Human pathologic wastes do not include the head or spinal column.
d. Medical sharps: Discarded sharps used in animal or human patient care, medical research, or clinical laboratories. This includes hypodermic needles; syringes; pipettes; scalpel blades; blood vials; needles attached to tubing; broken and unbroken glassware; and slides and coverslips.
e. Research animal wastes: Animal carcasses, body parts, and bedding of animals that have been infected with agents ~~which~~ that produce, or may produce, human infection.

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.
"Contaminate" formerly R18-13-1401(13)

ISSUE: The words "or infect" should be deleted since "infect" only refers to living organisms while "contaminate" refers to inanimate objects. "By the transfer of" should be changed to "with" for clarity. The definition would then read "...means to soil or stain with blood or other matter that may contain infectious agents."

ANALYSIS: ADEQ agrees.

RESPONSE: The definition has been changed to:
"Contaminate" or "contamination" means to soil or stain with blood or other matter that may contain infectious agents.

The following changes were made to R18-13-1401(13) as a result of GRRC staff review:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be deleted:

~~13. "Contaminate" or "contamination" means to soil, or stain with blood or other matter that may contain infectious agents.~~

ANALYSIS: ADEQ has agreed to delete this definition.

"Decontaminate" formerly R18-13-1401(14)

ISSUE: This definition is repeated in a clearer statement in R18-13-1407(A)(2)(c)(i-iii). This subsection should be deleted and replaced with definitions for "cleaning" and "disinfection," which clearly address the removal of infectious material from inanimate objects. These terms are used by generators, the Center for Disease Control and the Environmental Protection Agency (EPA), and we recommend consistency with their definitions. Any implication that the only method of decontamination is through the use of hot water is misleading.

Another commenter stated that the word "soil" was used inappropriately and that another term such as 'contamination' should be substituted in R18-13-1407(A)(2)(b).

ANALYSIS: ADEQ agrees with both comments.

RESPONSE: ADEQ has deleted the term "decontaminate" from the definition section and from the rule text. In addition, ADEQ has changed the section on "Packaging" found at R18-1407(A)(2)(b) to require "cleaning."

R18-13-1407(A)(2)(b) has been changed to:

Used for the storage or transport of biohazardous medical waste and cleaned after each use unless the inner surfaces of the container have been protected by disposable liners, bags, or other devices removed with the waste. "Cleaning" means agitation to remove visible particles combined with 1 of the following:

i Exposure to hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.

ii. Exposure to an EPA approved chemical disinfectant used under established protocols and regulations.

iii. Any other method that the Department determines is acceptable, if the determination of acceptability is made in advance of the cleaning.

R18-13-1401(12) "Discarded drugs" and "Regulated medical waste"

ISSUE: Several commenters stated that discarded drugs were not capable of transmitting disease to humans, and thus did not require "treatment" under these rules. At most, discarded drugs should simply be rendered unusable. This issue is related to the definition as proposed of "regulated medical waste" found at R18-13-1401(35), that included biohazardous medical waste, medical sharps waste, and discarded drugs. Commenters pointed out this rule language subjected discarded drugs to the treatment standards under the rule.

ANALYSIS: ADEQ agrees that discarded drugs do not require treatment. However, the definition of discarded drugs has been retained to identify those substances which are to be destroyed to prevent reuse.

RESPONSE: ADEQ will include a separate section, R18-13-1418, which provides a protocol for handling discarded drugs. In addition, the title of the Article will be changed to: "Biohazardous Medical Waste and Discarded Drugs" to reflect the fact that discarded drugs are not considered biohazardous medical waste. The definition of "Regulated Medical Waste" found at R18-13-1401(35) is deleted. A new Section, R18-13-1418 "Discarded Drugs" has been added which now reads:

A. A generator of discarded drugs not returned to the manufacturer shall destroy the drugs on site 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.

"Hard-plastic or metal container" formerly R18-13-1401(21)

The definition of "Hard-plastic or metal container" has been deleted, since it is no longer used in the rule text.

R18-13-1401(18) "Health care worker"

This definition was initially revised in response to a comment received regarding R18-1403(B)(7) described below.

The rule read:

"Health care worker" means, with respect to R18-13-1403(B)(7), a person who provides health care services at an off-site location which 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.

The following change was made as a result of GRRC staff review:
ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following citation be changed:
"Health care worker" means, with respect to R18-13-1403(B)~~(7)~~(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.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

"Medical sharps waste" formerly R18-13-1401(27)

ISSUE: This definition of medical sharps waste is unnecessary and should be deleted, since the definition of biohazardous medical waste already includes a definition of medical sharps.

ANALYSIS: ADEQ agrees that the term "medical sharps waste" is defined in R18-13-1401(5)(d) and the duplicative definition has been deleted.

RESPONSE: R18-13-1401(27) has been deleted.

R18-13-1401(22) "Medical waste"

ISSUE: As proposed, R18-13-1401(28) contained the word "treatment" used twice and may be misinterpreted because of the treatment definition in R18-13-1401(36). Also the term "discarded drugs" should be deleted.

ANALYSIS: This definition is now found at R18-13-1401(22) and ADEQ agrees that the statutory language for "medical waste" which is included in this definition is somewhat confusing. However, this definition is included in the rule to provide the reader with a statutory understanding of whether or not waste is governed under this medical waste rule. As a statutory definition, this term cannot be revised. Also, the term "discarded drug" is included in the statutory definition so it cannot be deleted. However, ADEQ has revised the definition of "treatment" now found at R18-13-1401(36) to clarify this term.

RESPONSE: The rule at R18-13-1401(36) has been changed to:

"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.

The following change to R18-13-1401(22) was made as a result of GRRC staff review:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following citation be changed:
"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(*~~5~~*) other than conditionally exempt small quantity generator waste*."

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(24) "Multi-purpose vehicle"

This definition has been changed for clarification and consistency. The rule now reads:

"Multi-purpose vehicle" means any motor vehicle operated by a health care worker, where the general purpose is the non-com-

mercial 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.

R18-13-1401(25) "Off site"

The statutory citation has been corrected.

The following change has been as a result of GRRC staff review:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

"Regulated medical waste" formerly R18-13-1401(35)

As noted above, the definition of "regulated medical waste" has been deleted.

"Sterilization" formerly R18-13-1401(38)

This definition of sterilization has been deleted because the term is no longer used in the rule.

R18-13-1401(32) "Technology provider"

The word "corporation" has been replaced with the word "person" so that the rule regulates persons.

R18-13-1401(35) "Transporter"

This definition of "transporter" has been changed to delete the word "intermediate" because there are no intermediate approved storage facilities.

R18-13-1401(37) "Treated medical waste"

The words "and may be disposed of in a municipal landfill" have been deleted because disposal in a municipal landfill is not the only option for treated medical waste. It may also be recycled.

R18-13-1401(40) "Treatment standards"

The citation to R18-13-1415 has been added to the definition of treatment standards for clarification.

The following change was made as a result of GRRC staff review:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

"Treatment standards" mean~~s~~ the level<u>s</u> of microbial inactivation, ~~as~~ prescribed in R18-13-1415, to be achieved for a specific type of biohazardous medical waste.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(41) "Universal biohazard symbol"

The following change was made as a result of GRRC staff review:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
"Universal biohazard symbol" <u>or "biohazard symbol</u>" 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, ~~1997~~ <u>1998)</u> 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.

ANALYSIS & RESPONSE: ADEQ agreed to make these changes.

R18-13-1401(42) "Vehicle not dedicated"

This definition, now found at R18-13-1401(42) has been revised to make it clearer and more understandable. The rule now reads:
"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(A)(7)

This term has been corrected to reflect the term disposal facility. The rule now reads:

An operator of a Department approved disposal facility who accepts untreated biohazardous medical waste.

R18-13-1402(A)(8), (9), and (10)

These 3 paragraphs have been added for clarification. The 1st 2 classes of generators were governed in the rule as proposed and have been broken out here for clarity.

A person who generates medical sharps in the preparation of human remains.

A person who generates medical sharps in the treatment of animals.

Subsection (10) clarifies that generators discarding drugs are subject to the provisions of the new R18-13-1418.

R18-13-1402(B)

ISSUE: This language could be made more clear by incorporating the following language:

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

ANALYSIS: ADEQ agrees.

RESPONSE: The rule was initially changed to:

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

The following change was made on the advice of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
The requirements for biohazardous medical waste set out for collection do not apply to the manner in which the generator collects or handles ~~and stores~~ biohazardous medical waste inside the generator's place of business.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1402(C)

This subsection has been deleted because it appears in R18-13-1401(41) under the definition of "treated medical waste."

R18-13-1403(A)(4) and R18-13-1403(B)(6)

ISSUE: Several commenters stated that the language of this exemption did not appear to reflect ADEQ's intent or the stakeholders recommendations on this issue. One commenter stated that as proposed, R18-13-1403(B)(6) creates a "conditional" exemption which applies only to persons who reside in a private, public or semi-public residence and generate regulated medical waste in the administration of self-care. The exemption does not extend to agents caring for exempt persons. As proposed, a provider of care to an exempt individual, whether a licensed health care provider, a family member or a volunteer would be subject to state regulation. The characterization of the exemption as "conditional" is not explained in the rule and could be seen to support a limitation of the exemption to persons named in the rule.

ANALYSIS: ADEQ agrees.

RESPONSE: The rule has been changed as follows: R18-13-1403(B)(6) has been deleted and R18-13-1403(A)(4) has been added. The rule now reads:

A household generator residing in a private, public, or semi-public residence who generates biohazardous medical waste in the administration of self care or the agent of the household generator who administers the medical care. This exemption does not apply to the facility in which the person resides if that facility is licensed by the Arizona Department of Health Services.

R18-13-1403(A)(5)

This exemption has been added for medical devices such as scissors and saw blades which are re-processed and returned to the generator.

R18-13-1403(A)(6)

This exemption has been included here to clarify that human remains are regulated under A.R.S. Title 36. However, medical sharps generated during the preparation of those remains are regulated under this Article, as described in R18-13-1403(B)(1).

R18-13-1403(A)(7)

This exemption has been moved from 1403(B)(3) to 1403(A)(7) because ADEQ removed the requirement to properly package, because this will be specified by the shipper. When this requirement was removed, the exemption became an absolute exemption, and not a conditional one predicated on proper packaging. The rule has been changed to:

A person who sends used medical sharps via the United States Postal Service or private shipping agent to a treatment facility.

R18-13-1403(B)(3)

This has now been addressed in R18-13-1403(A)(7).

R18-13-1403(B)(7)

ISSUE: The term "public health care worker" is confusing and misleading in R18-13-1403(B)(7). We suggest substituting both terms "health care worker or public health worker" as these are distinct occupations, either one of which may be conducting the activity to which this section refers.

ANALYSIS: ADEQ does not intend to limit the exemption to a public health care worker and for that reason, will refer to "health care worker."

RESPONSE: The rule at R18-13-1401(18) has been changed to:
"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.

R18-13-1403(B)(6)

Language has been added for clarification as follows:
A person who transports biohazardous medical waste between multiple properties separated by a public thoroughfare and which is owned or operated by the same owner or governmental entity is exempt from the requirements of R18-13-1409 if the person complies with R18-13-1403(B)(5)(a)-(e).

R18-13-1403(B)(7)
This exemption has been added to provide regulatory flexibility to hospitals who wish to collect medical sharps generated by staff physicians and then ship off-site for treatment or disposal. The rule now reads:
A hospital that chooses to accept medical sharps from staff physicians who generate medical sharps in a private practice is exempt from the requirement to obtain facility plan approval as long as the hospital collects medical sharps for off-site treatment or disposal.

R18-13-1403(C)(1)

The following change has been made to correct a citation. The rule is changed to:
A generator who treats biohazardous medical waste on-site and who accepts for treatment medical waste described in R18-13-1403(A)(4) is exempt from the requirement to obtain solid waste facility plan approval prescribed in R18-13-1410.

R18-13-1403(C)(2)
"A generator who contracts with a permitted transporter to transport biohazardous medical waste to a medical waste treatment or disposal facility is relieved of any obligation to retrieve and treat improperly disposed biohazardous medical waste after the transporter accepts possession."

The above language was stricken because there is no obligation to retrieve and treat for generators under these circumstances in the 1st place. Although an early version of this rule stated that the generator had responsibility to retrieve improperly disposed waste, this was removed in a previous proposed rule.

ISSUE: From a public health standpoint, it would be preferable not to require retrieval of improperly disposed of biohazardous waste at all. Untreated medical waste only poses a risk, if at all, when handled. Requiring additional handling of waste which has already been disposed of will increase, not reduce, public health risks.

ANALYSIS: ADEQ disagrees. Biohazardous medical waste improperly disposed of and that is readily accessible to unsuspecting persons or scavengers poses a health risk. This risk of exposure is greatly reduced by the requirement to retrieve improperly disposed waste.

RESPONSE: No change to the rule.

R18-13-1402(C)(2) (formerly (C)(3))
This exemption has been changed in 2 ways: first, language relative to liability is deleted because there is no obligation to retrieve and treat for generators under these circumstances in the 1st place. Although an early version of this rule stated that the generator had responsibility to retrieve improperly disposed waste, this was removed in a previous proposed rule. Second, the subsection now exempts self-hauling generators from the requirement to register as a transporter if they comply with packaging requirements found in R18-13-1403(B)(5)(a)-(e).

The rule now reads:
A generator who self-hauls biohazardous medical waste to a Department-approved medical waste treatment, storage, transfer, or disposal facility is exempt from the requirements of R18-13-1409 if the generator complies with R18-13-1403(B)(5)(a)-(e).

R18-13-1405

ISSUE: Where a doctor's office rents space from a hospital, can a hospital collect biohazardous medical waste for treatment that is generated by the doctor's office which is located on the same hospital campus?

ANALYSIS: Yes. ADEQ considers this on-site.

RESPONSE: No change to the rule.

R18-13-1405(D)(1)

The following wording was initially added for clarification. The rule was changed to:
A generator who autoclaves biohazardous medical waste on-site shall comply with all of the following conditions:

1. Further process by grinding, shredding or any other process, any recognizable human tissue, organs, body parts, and animals to render such waste non-recognizable and suitable for treatment.

R18-13-1405(D)(2)

As discussed earlier, the requirement to sterilize cultures and stocks has been eliminated. The rule now reads:
Operate the autoclave at the manufacturer's specifications appropriate for the quantity and density of the load.

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

D. A generator who autoclaves biohazardous medical waste on site shall comply with all of the following ~~conditions~~ requirements:
1. Further process by grinding, shredding, or any other process, any recognizable animals and human tissue, organs, or body parts, ~~and animals~~ to render such waste non-recognizable ~~and suitable for treatment~~ and ensure effective treatment.
2. Operate the autoclave at the manufacturer's specifications appropriate for the quantity and density of the load.
3. Keep records of operational performance levels for 6 months after each treatment cycle. Operational performance level recordkeeping ~~shall include~~ includes all of the following:
   a. Duration of time for each treatment cycle.
   b. The temperature and pressure maintained in the treatment unit during each cycle.
   c. The method used to determine treatment parameters ~~as set forth~~ in the manufacturer's specifications.
   d. The method in manufacturer's specifications used to confirm microbial inactivation and the test results.
   e. Any other operating parameters ~~as set forth~~ in the manufacturer's specifications for each treatment cycle.
4. Keep records of equipment maintenance for the duration of equipment use that include the date and result of all equipment calibration and maintenance.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1405(E)(2)

The following words were initially added for clarification, and for consistency with (D)(1) above. The rule now reads:
Further process by grinding, shredding or any other process, any recognizable human tissue, organs, body parts, and animals to render this waste non-recognizable and suitable for treatment.

The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.

R18-13-1405(F)(1)(b)

ISSUE: Treated biohazardous waste poses much less of a threat than ordinary municipal garbage. The rules do not impose and should not impose any special requirements on the disposal of treated biohazardous waste. Thus, the labeling requirement would serve no purpose. Requiring labeling will only result in unwarranted discrimination at landfills and increase disposal costs. These increased costs are not included in the EIS. This requirement should be deleted.

ANALYSIS: ADEQ disagrees with the statement that the labeling requirement would serve no purpose. Landfill workers need identification of red bags as either treated or untreated medical waste, since it is impossible to determine treatment by visual examination. This information serves landfill workers in making informed decisions about handling red bagged waste. Many landfills will not accept untreated medical waste.

RESPONSE: No change to the rule.

The following changes were made at the request of GRRC staff:

R18-13-1405(F)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

F. A generator shall do all of the following:

~~1. Package the treated medical waste.~~
   ~~a. According to the waste collection agency's requirements;~~
   ~~b. Attach to the package or container a label, placard, or tag with the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection. The generator shall ensure that the treated medical waste meets the standards of R18-13-1415.~~
~~2. Upon request of the solid waste collection agency or municipal solid waste landfill, provide a certification that the treated medical waste meets the standards of R18-13-1415.~~
~~3. Make treatment records available for Departmental inspection upon request.~~
~~4. Dispose of the treated medical waste at a Departmental approved municipal solid waste landfill or, if the waste was prepared for recycling as required by R18-13-1416, dispose at a Department approved solid waste recycling facility.~~
1. Package the treated medical waste according to the waste collection agency's requirements;
2. Attach to the package or container a label, placard, or tag with the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection as a general solid waste. The generator shall ensure that the treated medical waste meets the standards of R18-13-1415.
3. Upon request of the solid waste collection agency or municipal solid waste landfill, provide a certification that the treated medical waste meets the standards of R18-13-1415.
4. Make treatment records available for Departmental inspection upon request.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1405(F)(4)

This language is unnecessary and has been deleted because R18-13-1401(41) defines treated medical waste and explains that treated medical waste is considered solid waste.

R18-13-1405(G)

This language was initially revised to reflect the addition of a separate section, R18-13-1419. The requirement to prevent a stick hazard was found in the new section. The rule read:
Medical sharps shall be handled as described in R18-13-1419. The text of R18-13-1419 reads:
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.

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.

The following change was made at the request of GRRC staff:

R18-13-1405(G)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
G. ~~Medical~~ A generator of medical sharps shall ~~be handled as described~~ handle medical sharps as prescribed in R18-13-1419.
ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1405(H)

ISSUE: When biohazardous or any medical waste can be treated onsite by encapsulation there is no need to require further treatment such as sterilization or disinfection. This encapsulated product would be safe to discard through the regular landfill disposal method. Another commenter stated a concern that encapsulation was by itself an adequate treatment option and such would be prohibited.

ANALYSIS: ADEQ agrees. The requirements for medical sharps are now found in R18-13-1419 and there is no requirement for the encapsulating agent to meet treatment standards. However, subsection H. has been revised in order to list proper handling for chemotherapy waste and animal waste. Medical sharps were previously required to be treated, and R18-13-1419 represents no change to that requirement, only a reformatting. With respect to cultures and stocks, the requirement for sterilization has been dropped and the packaging requirements for off site transportation of untreated cultures and stocks are explained in more detail in order to be more consistent with the United States Department of Transportation requirements for the shipment of hazardous materials.

RESPONSE: R18-13-1405(H) was changed to read:
Chemotherapy waste, cultures and stocks and animal waste shall be handled as described in R18-13-1420.

The following change was made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
~~**H.** Chemotherapy waste, cultures and stocks and animal waste shall be handled as described in R18-13-1420.~~
H. A generator of chemotherapy waste, cultures or stocks, or animal waste shall handle that waste as prescribed in R18-13-1420.
ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1406(B)

This language has been added to R18-13-1406(B) to provide clarification. The rule now reads:
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 1 year from the date of acceptance by the transporter. The tracking document shall contain all of the following information:

1. Name and address of the generator, transporter, and medical waste treatment, storage, transfer, or disposal facility, as applicable.
2. Quantity of biohazardous medical waste collected by weight, volume, or number of containers.
3. Identification number attached to bags or containers.
4. Date the biohazardous medical waste is collected.

R18-1406(C) and (D)

These references have been added to reference 2 new sections for waste with additional handling requirements. These sections now read:
C. A generator of chemotherapy waste, cultures and stocks, or animal waste shall handle the waste as prescribed in R18-13-1420.

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

R18-13-1407(A)(1)

ISSUE: The requirement that a red bag be of sufficient thickness to prevent breakage is not feasible. Substitute the word "leakage" for the word "breakage" because a plastic bag that won't break would become a rigid container not a bag. There is no reason to have a bag that won't break if it is required to be placed in a secondary container. Another commenter stated that the language was vague and provides no guidance to generators.

ANALYSIS: ADEQ has revised the standards for red bags by using the packaging requirements as set forth by the U.S. Department of Transportation in its regulations for infectious substances and regulated medical waste.

RESPONSE: The rule now reads:

A. A generator who sets biohazardous medical waste out for collection for off-site treatment or disposal shall package the biohazardous medical waste in either of the following:
1. A red disposable plastic bag that is:
   a. Leak resistant,
   b. Impervious to moisture,
   c. Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling,
   d. Sealed to prevent leakage during transport,
   e. Puncture resistant for sharps, and
   f. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and bear the universal biohazard symbol. The secondary container may be either disposable or reusable.

ISSUE: The rule includes a redundant definition of universal biohazard symbol. The term is already defined at R18-13-1401(49)

ANALYSIS: ADEQ agrees.

RESPONSE: This redundant definition is deleted.

R18-13-1407

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
R18-13-1407. Packaging ~~of Biohazardous Medical Waste~~

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1407(A)(2)

ISSUE: The phrase "A reusable container or bag that bears the universal biohazard symbol and that is" is confusing. Please delete the words "or bag" so that the sentence reads: "A reusable container that bears the universal biohazard symbol and that is"

ANALYSIS: ADEQ agrees.

RESPONSE: The rule has been changed to:
2. A reusable container that bears the universal biohazard symbol and that is:
   a. Leak-proof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water,

R18-13-1407(A)(2)

ISSUE: The language of this provision is confusing. Section R18-13-1407(A)(2) was much easier to follow and should be substituted.

ANALYSIS: Although ADEQ received another comment on this section suggesting use of a different term than "decontaminated" there was no other mention of any confusion.

RESPONSE: Subsection (2)(b) was initially moved to subsection (D). The new subsection (D) read:
Disposable packaging and liners shall be managed as biohazardous medical waste and not reused.

R18-13-1407(A)(2)(c)

ISSUE: The terms "decontaminated" and "decontamination" are not used here in a manner consistent with their use in health care. Containers should be "cleaned" (consistent with your definition of "decontamination") and then "disinfected" as with an EPA approved disinfectant.

ANALYSIS: ADEQ agrees.

RESPONSE: This change has been made and the word "cleaned" is used throughout the text.

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

A. A generator who sets biohazardous medical waste out for collection for off-site treatment or disposal shall package the biohazardous medical waste in either of the following:
1. A red disposable plastic bag that is:
   a. Leak resistant,
   b. Impervious to moisture,
   c. Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling,
   d. Sealed to prevent leakage during transport, ~~and~~
   e. Puncture resistant for sharps, and
   f. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and ~~which~~ bear~~s~~ the universal biohazard symbol. The secondary container may be either disposable or reusable.
2. A reusable container that bears the universal biohazard symbol and that is:
   a. Leak-proof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water, and
   b. Used for the storage or transport of biohazardous medical waste and cleaned after each use unless the inner surfaces of the container have been protected ~~from contamination~~ by disposable liners, bags, or other devices removed with the waste. ~~"Cleaned"~~ "Cleaning" means agitation to remove visible ~~contamination~~ particles combined with 1 of the following:
      i. Exposure to ~~an EPA-approved chemical disinfectant used under established protocols and regulations.~~ hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.
      ii. Exposure to an EPA-approved chemical disinfectant used under established protocols and regulations.
      iii. Any other ~~manner~~ method that the Department determines is acceptable, if the determination of acceptability is made in advance of the ~~decontamination.~~ cleaning.

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.

R18-13-1407(B)

The words "or that is disposable packaging" have been added to clarify that a container not cleaned or that is disposable must be handled as biohazardous medical waste.

R18-13-1408.
The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
R18-13-1408. Storage ~~of Biohazardous Medical Waste~~

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1408(B)(1)

ISSUE: This paragraph purports to regulate storage inside the generator's place of business and is therefore inconsistent with proposed R18-13-1402(B).

ANALYSIS: As previously stated, ADEQ has no intent to regulate inside the generator's place of business.

RESPONSE: The rule was initially changed to:
Once biohazardous medical waste has been packaged for shipment off-site, a generator shall provide a storage area for the storage of biohazardous medical waste until the waste is collected and shall meet both of the following:
1. Secure the storage area in such as way that restricts access to, or contact with the biohazardous waste to authorized persons.

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding, the following be changed:

B. Once biohazardous medical waste has been packaged for shipment off site, a generator shall provide a storage area for biohazardous medical waste until the waste is collected and shall ~~meet~~ comply with both of the following requirements:
   1. Secure the storage area in ~~such a way~~ a manner that restricts access to, or contact with the biohazardous medical waste to authorized persons.
   2. Display the universal biohazard symbol and post warning signs worded as follows for medical waste storage areas: (in English) "CAUTION -- BIOHAZARDOUS MEDICAL WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and (in Spanish) "PRECAUCION -- ZONA DE ALMACENAMIENTO DE DESPERDICIOS BIOLOGICOS PELIGROSOS -- PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS."

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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 if it does not create a nuisance. However, refrigerate at 40° F. or less putrescible biohazardous medical waste ~~may no be~~ kept ~~longer~~ more than 7 days ~~unless it is refrigerated at 40° F. or less~~.
   2. 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 ~~described~~ prescribed in R18-13-1412.
   3. Keep the storage area free of visible contamination.
   4. Protect ~~regulated~~ biohazardous medical waste from contact with water, precipitation, wind, or animals. ~~The waste shall not provide a breeding place or a food source for insects or rodents.~~ A generator shall ensure that the waste does not provide a breeding place or a food source for insects or rodents.
   5. Handle spills by re-packaging the biohazardous medical waste, re-labeling the containers and ~~decontaminating~~ cleaning any soiled surface ~~as described in R18-13-1407(A)(2)(c).~~ as prescribed in R18-13-1407(A)(2)(b).
   6. Notwithstanding ~~paragraph 1 of this~~ subsection (C)(1), if odors become a problem, a generator shall minimize objectionable odors and the off-site migration of odors. ~~The Department may require the waste to be removed after 3 days or the waste to be refrigerated.~~ If the Department determines that a generator has not acted or adequately addressed the problem, the Department shall require the waste to be removed or refrigerated at 40° F or less.

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.

R18-13-1409(D)

The rule was initially revised for clarity and for consistency with R18-13-1406(B), and to use the proper term "Department approved transfer, storage, treatment, or disposal facility." The rule read:
A transporter who accepts biohazardous medical waste from a generator shall leave a copy of the tracking document described in R18-13-1406(B) with the person from whom the waste is accepted. 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.

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

D. A transporter who accepts biohazardous medical waste from a generator shall leave a 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 ~~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.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1409

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

R18-13-1409. Transportation ~~of Biohazardous Medical Waste~~

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1409(E)

The rule was initially revised for clarification that the vehicle must be locked at all times except during loading and unloading. The rule read:

A transporter who transports biohazardous medical waste in a vehicle dedicated to the transportation of biohazardous medical waste shall ensure that the cargo compartment can be secured to limit access to authorized persons at all times except during loading and unloading. In addition, the cargo compartment shall be constructed in compliance with ~~one~~1 of the following:

The following change has been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

E. A transporter who transports biohazardous medical waste in a vehicle dedicated to the transportation of biohazardous medical waste shall ensure that the cargo compartment can be secured to limit access to authorized persons at all times except during loading and unloading. In addition, the cargo compartment shall be constructed in compliance with 1 of the following:

1. Have a fully enclosed, leak-proof cargo compartment consisting of a floor, sides, and a roof that are made of ~~an impervious material, or material that is otherwise sealed~~ 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 ~~an impervious and non-porous material.~~ a non-porous material impervious to biohazardous medical waste.
3. Tow a fully enclosed leak-proof trailer made of ~~an impervious and non-porous material.~~a non-porous material impervious to biohazardous medical waste.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1409(F)

The term "commerce" has been deleted, and the phrase "30 consecutive days" has been used to clarify the Department's intent.

The following has been changed at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

F. 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, shall comply with the following:

1. Subsection (A) and ~~(E).~~ (C) through (G)
2. Clean the vehicle ~~before it is used again~~. as prescribed in R18-13-1407(A)(2)(b) before it is used for another purpose.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1409(G)(2)

The rule was initially revised for clarity. The rule read:

Accept biohazardous medical waste only after providing the generator with a signed tracking form as described in R18-13-1406(B) and keep a copy of the tracking document for 1 year.

R18-13-1408(G)(3)

The rule was initially revised for clarity. The rule read:
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 at 40° F. or less until delivery, not to exceed 90 days.

R18-13-1408(G)(6) and (7)

These paragraphs are redundant because they are included elsewhere. They have been deleted.

The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

G. A person who transports biohazardous medical waste shall comply with all of the following:
1. Accept only biohazardous medical waste packaged as ~~described~~ prescribed in R18-13-1407.
2. Accept biohazardous medical waste only after providing the generator with a signed tracking form as ~~described~~ prescribed in R18-13-1406(B), and keep a copy of the tracking document for 1 year.
3. Deliver biohazardous medical waste to a Department-approved biohazardous medical waste storage, transfer, treatment, or disposal facility within 24 hours of collection or refrigerate the waste for not more than 90 days at 40° F. or less until delivery.
4. Not hold biohazardous medical waste longer than 96 hours in a refrigerated vehicle unless the vehicle is parked at a Department-approved facility.
5. 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 ~~coupled and uncoupled~~ uncoupled and coupled to another cargo vehicle or truck trailer as long as the biohazardous medical waste is not removed from the cargo compartment.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1410(A)

This statutory reference has been updated.

The following changes have been made at the request of GRRC staff.

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

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

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

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

ANALYSIS & RESPONSE: ADEQ agreed to make these changes.

R18-13-1411.
The following change has been made at the request of GRRC staff.

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

R18-13-1411. ~~Medical Waste~~ Storage and Transfer Facilities: Design and Operation

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1411(8)

The rule has been revised for clarity. The rule now reads:
Clean the storage area daily as described in R18-13-1407(A)(2)(c).

The following changes have been made at the request of GRRC staff.

ISSUE: GRRC staff requested that the following be changed:

R18-13-1411. ~~Medical Waste~~ Storage and Transfer Facilities; Design and ~~Operational Requirements.~~ Operation
An operator of a storage facility or transfer facility shall ~~be in compliance~~ comply with all of the following design and operation requirements:

1. ~~The facility shall be designed~~ Design the facility so that ~~regulated~~ biohazardous medical waste is always handled and stored separately from other types of solid waste if accepted at the facility.
2. Display prominently the universal biohazard symbol ~~and post warning signs worded~~ as ~~described~~ prescribed in R18-13-1401.
3. Construct the storage area from smooth, easily cleanable non-porous material~~s~~ that ~~are~~ is impervious to liquids and resistant to corrosion by disinfecting agents and hot water.
4. Protect ~~regulated~~ biohazardous medical waste from contact with water, precipitation, wind, or animals.
5. Specify in the application for facility plan approval the maximum storage time that ~~regulated~~ biohazardous medical waste ~~shall~~ will remain at the facility. If the ~~regulated~~ biohazardous medical waste will be stored for ~~longer~~ more than 24 hours, the operator shall equip the facility ~~shall be equipped~~ with a refrigerator to refrigerate the ~~regulated~~ biohazardous medical waste. The operator of the facility shall maintain the temperature in the refrigerator at 40° F. or ~~lower.~~less.
6. Accept ~~regulated~~ biohazardous medical waste only if it is accompanied by the tracking form. The operator shall sign the tracking form and keep a copy of the acceptance documentation for ~~a period of one~~ 1 year;
7. Accept ~~regulated~~ biohazardous medical waste if it is packaged as described in R18-13-1407. If a ~~regulated~~ biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a transfer facility operator shall do ~~one~~1 of the following:
   a. Reject the waste and return it to the ~~generator~~ transporter.
   b. Accept the waste and immediately repackage it as ~~described~~ prescribed in R18-13-1407(A).
8. ~~Decontaminate~~ Clean the storage area daily as ~~described~~ prescribed in R18-13-1407(A)(2)~~(c)~~. ~~on a regular basis and after any spills.~~

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.

R18-13-1412(A)(1)

The rule was initially revised for clarity. The rule read:
An operator who applies for facility plan approval shall comply with all of the following:
1. Submit to the Department documentation for all of the following equipment specifications:

R18-13-1412(A)(3)

The rule was initially revised for clarity. The rule read:
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 which require compliance with both of the following: **...**

In addition, the word "generator" was replaced with "transporter" in (A)(3)(b)(i) to correct an error.

R18-13-1412(A)(7), (8), (9) and (10)

These were initially added for clarity and to put them in 1 place in the rule text. The remaining text has been renumbered. The rule read:

7. Autoclaving, when done in accordance with manufacture's specifications for the unit.

8 Use an alternative medical waste treatment method that meets the treatment standards set forth in R18-13-1415(E).

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

10. Treat medical sharps as described in R18-13-1419.

The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

A. An operator who applies for facility plan approval shall comply with all of the following:
1. Submit to the Department the following documentation: ~~for all of the following equipment specifications:~~
   a. Equipment specifications that identify the proper type of medical waste to be treated in the equipment and any design or equipment restrictions.
   b. Manufacturer's specifications and operating procedures for the equipment that describe the type and volume of waste to be treated, monitoring data of the treatment process, and calibration and testing of the equipment, ~~that detail~~ providing specific details about the capability of the equipment to achieve the treatment standards ~~described~~ prescribed in R18-13-1415.
   c. Instructions for equipment maintenance, testing, and calibration that ensure the equipment achieves the treatment standards ~~described~~ prescribed in R18-13-1415.
   d. Training manual for the equipment.
   e. Written certification from the manufacturer stating that the equipment, when operated properly, is capable of achieving the treatment standards ~~described~~ prescribed in R18-13-1415.
2. Submit to the Department and have readily available at the facility, an operations procedure manual describing how the waste will be handled from the time it is accepted by the treater through the treatment process and final disposition of the treated waste. The operations procedure~~s~~ manual shall include all of the following:
   a. Provisions for treating biohazardous medical waste within 24 hours of receipt or refrigerating immediately at 40° F. or ~~lower~~ less upon determination that treatment or disposal will not occur within 24 hours.
   b. A contingency plan if the treatment equipment is out of service for an extended period of time. The plan shall address the manner and length of time for storage of the waste. ~~The length of time the regulated~~ An operator shall not store biohazardous medical waste ~~can remain in storage shall not exceed~~ more than 90 days. ~~and~~ The plan shall be based on the capacity of the treatment equipment to treat ~~the~~ all waste at the facility, including any backlog of stored waste ~~together with the ongoing operations~~ and any new waste intake. If the 90 day time-frame will be exceeded, the operator shall either stop accepting waste until the backlog is treated, or contract with another treatment facility ~~to assist in~~ for treating the waste.
   c. Procedures for handling hazardous chemicals, radioactive waste, and chemotherapy waste. The plan shall provide for scanning biohazardous medical waste with a Geiger counter and handling wastethat measures above background level in ~~compliance~~ a manner that complies with with state and federal law.
3. Have on hand written procedures stating that biohazardous medical waste is to be accepted from a transporter only if the waste is accompanied by a tracking form, and written procedures ~~which~~ that require compliance with both of the following:
   a. ~~Sign~~ The treater or the treater's authorized agent shall sign the tracking document and keep a copy of the acceptance documentation for ~~a period of~~ 1 year.
   b. If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do ~~one~~1 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 ~~shall~~ either ~~have~~ has a curb of sufficient height to contain spills or ~~shall slope~~ slopes to a drain that connects to an approved sanitary sewage system, ~~approved~~ septic tank system, or collection device.
5. Store biohazardous medical waste as required in R18-13-1408(~~E~~).
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. ~~Perform a waste determination of~~ Determine whether the ash ~~to determination whether the ash~~ is hazardous waste as ~~described in~~ 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.
~~7.~~11. Keep records of equipment maintenance and operational performance levels for 3 years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall ~~include~~ indicate the duration of time for each treatment cycle ~~as follows~~ 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 ~~as set forth~~ 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.

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.

R18-13-1414(A)(9)

ISSUE: The United States Environmental Protection Agency (USEPA) has requested that registration for alternative medical waste treatment methods include documentation of registration where required by A.R.S. § 3-351. This statute requires that pesticides be licensed with the Arizona Department of Agriculture.

ANALYSIS: ADEQ agrees.

RESPONSE: The rule initially read:

Documentation of registration where required by A R.S. § 3-351.

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

7. Written documentation demonstrating ~~that demonstrates~~ that the alternative medical waste treatment method is capable of compliance with the treatment standards in this Article for the type of waste treated. ~~The demonstration shall be made by~~ The manufacturer shall employ a laboratory independent of any oversight activities by the manufacturer to provide this analysis.
8. The manufacturer's equipment specifications for the alternative medical waste treatment method being registered, including all of the following:
   a. Unit model number, or serial number.

b. Equipment specifications that identify the proper type of ~~regulated~~ biohazardous medical waste to be treated by the equipment and any design or equipment restrictions.
c. Operating procedures for the equipment that ensure the equipment complies with the treatment standards ~~described~~ prescribed in this Article for the type of waste treated.
d. Instructions for equipment maintenance, testing, and calibration that ensure the equipment complies with the treatment standards ~~described~~ prescribed in this Article for the type of waste treated.

9. Written documentation of registration if required by A R.S. § 3-351.

B. The Department shall make a determination whether ~~or not~~ to approve the registration application. If the Department approves the application, it shall issue to the applicant a certification of registration containing an alternative medical waste treatment method registration number ~~to the applicant.~~ Only an alternative technology method with a valid Department issued registration number ~~shall qualify as meeting~~ meets the requirements of this Article.

ANALYSIS & RESPONSE: ADEQ agreed to make these changes.

R18-13-1415

ADEQ has relied upon the treatment standard data found in The "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" that was updated in December, 1998 (Manual). During the public comment period, ADEQ stated its intent to incorporate the treatment calculations found in the Manual for its proposed treatment standards found in R18-13-1415 and has made copies of the Manual available to interested stakeholders.

As discussed below, changes have been made in order to maintain consistency with the revised and simplified manual. In addition, ADEQ has been informed that it was advised in error on the proposed rule that the proper standard is either inactivation of vegetative microorganisms or spores. ADEQ does not consider this a substantial change because ADEQ has been clear to stakeholders about its intent to follow the instructions in the Manual, and because ADEQ is aware that those stakeholders required to meet the standards of R18-13-1415 are aware of the correct testing protocols as outlined in the Manual, and have access to the Manual.

With regard to the simplification of the biological indicators found in R18-13-1415(B), all but mycobacteria has been deleted based upon the recommendations of the STAATT II manual. The Manual explains: "It has become apparent in the tests performed with many different technologies as required by state regulatory agencies, that the use of additional biological indicators provides no additional safeguards to public health and safety by further ensuring the efficient operations of treatment systems. However, they do significantly add to costs of efficacy tests conducted by independent laboratories funded by the manufacturers. It was argued in STAATT II that the use of bacterial spores as the sole biological indicator provides a margin of safety beyond the inactivation of vegetative bacteria, fungi, viruses, parasites, and mycobacteria. Therefore, a reduction in the number of biological indicator organisms used for efficacy testing should now be considered." The STAATT manual continues: "...After considerable discussion, the STAATT II participants recommended at a minimum a 6 log reduction in the concentration of Mycobateria bovis BCG, M. Phlei or other species of mycobacteria and a 4 log reduction in the level of Bacillus spores. The participants believed that the factors which contributed to the initial recommendations to achieve these Level III inactivation parameters are still valid today."

In addition, reorganizational changes have been made and the material in R18-13-1415(A) through (D) is found elsewhere as described earlier.

R18-13-1415(A) read:

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

R18-13-1415(B) read:

B. A treater utilizing an alternative treatment method shall conduct efficacy studies to demonstrate that the treatment mechanisms are capable of achieving the standards set forth in subsection (A) through both of the following:
1. Mycobacterial species used as indicators of vegetative microorganisms:
   a. *Mycobacterium phlei*, or
   b. *Mycobacterium bovis* (BOG) (ATCC 35743), and

2. Spore suspensions of 1 of the following 2 bacterial species, as appropriate to the technology, used as biological indicators in efficacy tests of thermal, chemical and irradiation treatment systems. Studies shall demonstrate a 4 $\log_{10}$ reduction in the concentration of viable spores, through the use of an initial inoculum suspension of 5 $\log_{10}$ or greater of:
   a. *Bacillus stearothermophilus* (ATCC 7953), or
   b. *Bacillus subtilis* (ATCC 19659).

Since GRRC submission, this rule text has been changed back to the proposed language. Please see the discussion at the end of this section under "Changes Made by ADEQ After GRRC Submission" which explains the ADHS advice on this issue.

ISSUE: ADEQ should define chemotherapy waste and clarify whether R18-13-1412(A)(2)(b) also includes trace chemotherapy. This provision requires that a medical waste treatment facility have procedures for handling chemotherapy waste.

ANALYSIS: Chemotherapy waste is defined as any waste that comes in contact with chemotherapy.

RESPONSE: No change to the rule.

R18-13-1415(B)(1)

ISSUE: In general, high levels of disinfection may be appropriate for cultures and stocks, due to high concentrations of organisms present. There is no rational basis, however, for requiring sterilization of such laboratory wastes, nor for requiring high level disinfection of ordinary "biohazardous medical waste." Standards requiring disinfection of such wastes to levels of organisms below what may be commonly found in household trash (for example, in used facial tissues, soiled diapers and sanitary napkins) cannot be defended on any scientific basis.

Another commenter stated that ADEQ's proposal to require sterilization of cultures and stocks rests on 2 misconceptions: that sterilization will increase protection of public health and that requiring sterilization will have little effect on biohazardous waste generators. In fact high level disinfection is more than sufficient to eliminate any threat of disease transmission from biohazardous wastes generated by the healthcare industry. Requiring a higher standard will effectively preclude many healthcare facilities from employing alternative technologies, which ultimately drive up waste treatment costs for all healthcare providers.

Another commenter stated that cultures and stocks should receive high disinfection, except that Bacillus anthracis (anthrax) should be identified as requiring sterilization. In addition, the commenter suggested that under research animal waste: delineating anthrax, Q fever and prion-related diseases (such as scrapie, TSE and BSE) as requiring incineration.

ANALYSIS & RESPONSE: ADEQ agrees. However, a new section, R18-13-1420 "Additional Handling Requirements for Certain Wastes" has been added, and this provision appears there.

R18-13-1415(E)(1)(d)

ISSUE: Several commenters stated that the rule requirements were "overkill" and that untreated medical waste failed to pose a substantial risk to human health and the environment.

ANALYSIS: ADEQ agrees that there is a difference of scientific opinion as to the likelihood of disease transmission from biohazardous medical waste. However, stakeholders involved in the handling and landfilling of solid waste have communicated to the department their concern regarding the potential transmission of disease from biohazardous medical waste. This concern has resulted in a decision by many landfills not to accept untreated medical waste. ADEQ recognizes that regardless of whether a consensus exists regarding the potential for disease transmission, the present practice is that most Arizona landfills refuse to accept untreated medical waste.

RESPONSE: No change to the rule.

ISSUE: ADEQ considered 2 related issues with respect to R18-13-1415(E)(1). First, it received a comment that Cryptosporidium spp. oocysts cannot be grown in vitro to determine viability, and therefore should be deleted.

Secondly, ADEQ has learned that the Treatment Manual has been simplified to require only the representative biological

indicators of *B. Stearothermophilus* and *B.subtilis* and *Mycobacteria* be demonstrated.

RESPONSE: This provision is now found at R18-13-1415(B)(1) which now reads:

1. Mycobacterial species used as indicators of vegetative microorganisms:
   a. *Mycobacterium phlei*, or
   b. *Mycobacterium bovis* (BOG) (ATCC 35743)

The following changes were made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

~~**D.** Any methodology employed to determine treatment efficacy of the technology shall assure required microbial inactivation and shall assure that the protocols are congruent with the treatment method. Acceptable demonstration of compliance is required to be provided by an independent testing laboratory.~~

ANALYSIS: ADEQ has agreed to make these changes.

RESPONSE: The rule now reads:

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

R18-13-1416(A)

ISSUE: The citation in R18-13-1416(A) should read R18-13-1407 and not R18-13-1409.

ANALYSIS: ADEQ agrees.

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

R18-13-1417(4)

ISSUE: ADEQ should clarify whether the language in paragraph 4. "Do not drive directly over deposited medical waste, achieve compaction by 1st spreading a layer of soil..." indicates that daily cover is limited to "soil" or whether alternative daily cover can be used.

ANALYSIS: ADEQ declines to allow alternate daily cover.

RESPONSE: No change to the rule.

ISSUE: ADEQ should not allow untreated medical waste to be accepted at approved landfills. Such wastes from HIV and HBV research laboratories will be prohibited under 29 CRF 1910.1030(e)(2)(ii)(H) at landfills. Also, healthcare institutions listed in Article 2 and Article 3 of Title 9, Chapter 10 of the Arizona Administrative Code requires treatment of regulated medical waste.

ANALYSIS: ADEQ does not intend to change any duties or responsibilities that a landfill has with regard to federal regulations. R18-13-1314 allows a landfill to make a choice of whether or not to accept untreated medical waste, and if untreated biohazardous medical waste is accepted, ADEQ must approve the disposal facility plan which addresses the operating standards described in R18-13-1314.

With regard to the Arizona Department of Health Services regulations adopted in 1979, because the Legislature has so recently directed ADEQ to regulate the storage, collection, transportation, treatment and disposal of medical waste ADEQ believes these proposed rules govern over the earlier, more limited regulations. This has been the position of ADEQ since it proposed

the rule in 1996.

RESPONSE: No change to the rule.

The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

R18-13-1417. Disposal Facilities; ~~Operational Requirements~~ Operation
An operator of a municipal solid waste landfill that accepts untreated ~~regulated~~ biohazardous medical waste shall ~~demonstrate compliance with all of the following in its facility plan:~~ comply with all the following design and operational requirements:

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

ANALYSIS & RESPONSE: ADEQ agreed to make these changes.

R18-13-1418
This section was initially added. There is no change in the regulation of discarded drugs, this is a reformatting change. The rule read:

A. Discarded drugs not returned to the manufacturer shall be destroyed prior to placing the waste out for collection. Destruction of discarded drugs shall be by any method which prohibits the drug's use. Where federal or state law prescribes the destruction of discarded drugs that law shall be followed
B. Discarded drugs may be flushed down a sanitary sewer if allowed by the waste water treatment authority.

The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

~~**A.** Discarded drugs not returned to the manufacturer shall be destroyed prior to placing the waste out for collection. Destruction of discarded drugs shall be by any method which prohibits the drug's use. Where federal or state law prescribes the destruction of discarded drugs that law shall be followed~~
~~**B.** Discarded drugs may be flushed down a sanitary sewer if allowed by the waste water treatment authority.~~

ANALYSIS: ADEQ has agreed to make these changes.

RESPONSE: The rule now reads:
Discarded Drugs. R18-13-1418.

A. A generator of discarded drugs not returned to the manufacturer shall destroy the drugs on site 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.

Medical Sharps. R18-13-1419
This section was initially broken out separately to provide clarity on the handling of this category of medical sharps. This is a formatting change and does not represent a change in how they are regulated other than what has been explained above. The rule read:

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 and render them incapable of creating a stick hazard by using an encapsulation agent or process. 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.
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. Process to prevent a stick hazard.

The following change has been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

~~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 and render them incapable of creating a stick hazard by using an encapsulation agent or process. 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.~~
   ~~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. Process to prevent a stick hazard.~~

ANALYSIS: ADEQ has agreed to make this change.

RESPONSE: The rule now reads:

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.
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.

R18-13-1420

This section has been broken out separately and does not represent a change in how these wastes are handled other than what has been explained above. The rule initially read:

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:
      a. 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 secondary inner container which is then placed inside an outer container, and
      b. The primary inner container shall be capable of withstanding internal pressure of 95 kpa at -40 degrees to 130 degrees Fahrenheit. The outer packaging shall be at least 3.9 inches at its smallest external dimension and capable of passing a 30 foot drop test, a penetration test, and the vibration standard. The outer rigid container shall display the biohazardous symbol and a list of contents by biohazardous class.
   2. Chemotherapy waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
   3. Experimental or research animal waste shall be handled as follows:
      a. Autoclave bedding on site or package as described in R18-13-1407 for off site treatment or landfilling.
      b. Incinerate animal carcasses on-site, or if taken off-site for treatment meet 1 of the following:
         i. Package in a leakproof, covered container, label the contents and send to an incinerator or a Department approved landfill, or

ii. If treated by a method other than incineration, pre-process by grinding, then treat by a method which achieves the standards of R18-13-1415(A).

B. If grinding is used in combination with another treatment method described in this Article, it shall be conducted in a closed system to prevent exposure of the waste to humans and the environment. If grinding is used for medical sharps, this grinding shall render the medical sharps incapable of creating a stick hazard.

The following changes have been made at the request of GRRC staff:

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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:~~

~~a. 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 secondary inner container which is then placed inside an outer container, and~~

~~b. The primary inner container shall be capable of withstanding internal pressure of 95 kpa at -40 degrees to 130 degrees Fahrenheit. The outer packaging shall be at least 3.9 inches at its smallest external dimension and capable of passing a 30 foot drop test, a penetration test, and the vibration standard. The outer rigid container shall display the biohazardous symbol and a list of contents by biohazardous class.~~

~~2. Chemotherapy waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.~~

~~3. Experimental or research animal waste shall be handled as follows:~~

~~a. Autoclave bedding on site or package as described in R18-13-1407 for off site treatment or landfilling.~~

~~b. Incinerate animal carcasses on-site, or if taken off-site for treatment meet one of the following:~~

~~i. Package in a leakproof, covered container, label the contents and send to an incinerator or a Department approved landfill, or~~

~~ii. If treated by a method other than incineration, pre process by grinding, then treat by a method which achieves the standards of R18-13-1415(A).~~

~~**B.** If grinding is used in combination with another treatment method described in this Article, it shall be conducted in a closed system to prevent exposure of the waste to humans and the environment. If grinding is used for medical sharps, this grinding shall render the medical sharps incapable of creating a stick hazard.~~

ANALYSIS: ADEQ has agreed to make these changes.

RESPONSE: The rule now reads:

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 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 secondary inner container that is then placed inside an 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 waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
3. Experimental or research animal waste shall be handled as follows:
   a. Autoclave bedding on site or package as described in R18-13-1407 for off- site treatment or landfilling.
   b. Incinerate animal carcasses on site, or if taken off site for treatment, comply with 1 of the following requirements:
      i. Package the waste in a leakproof, covered container, label the contents and send to an incinerator or a Department-approved landfill, or
      ii. If treated by a method other than incineration, pre-process by grinding, then treat by a method that achieves the standards of R18-13-1415(A).

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

THE FOLLOWING ADDITIONAL RULE TEXT CHANGES WERE MADE AT THE REQUEST OF GRRC STAFF

R18-13-1401(8) "Blood and blood products"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
"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 ~~licensed~~ products.
ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

"Body fluids" formerly R18-13-1401(9)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be deleted:
~~9. "Body fluids" means any substance that emanates or originates from the human body including: tissue, semen, vaginal secretions, cerebro-spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Feces, nasal secretions, sputum, sweat, tears, urine, or vomitus are "body fluids" for the purposes of this Article only if they contain visible blood.~~

ANALYSIS & RESPONSE: ADEQ has agreed to delete this definition.

"Collection" formerly R18-13-1401(12)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be deleted:
~~12. "Collection" means the pick-up of biohazardous medical waste from the generator's waste accumulation or storage area by a transporter for the purpose of transporting the waste away from the generator's facility to a Department approved medical waste storage, treatment, or disposal facility. Collection does not include waste pick-up by a janitorial service that occurs within the generator's place of business, if the waste is not removed from the generator's place of business.~~

ANALYSIS & RESPONSE: ADEQ has agreed to delete this definition.

R18-13-1401(11) "Dedicated vehicle"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
"Dedicated vehicle" means a motor vehicle or trailer that is pulled by a motor vehicle ~~and that is~~ used by a transporter for the sole purpose of transporting biohazardous medical waste.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(12) "Discarded drug"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:
"Discarded drug" means any prescription medicine, over-the-counter medicine, or controlled substance, used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to ~~dispose~~ abandon. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(15) "Free flowing"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(16) "Generator"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

"Generator" means a person whose act or process produces biohazardous medical waste, or a discarded drug, or whose act 1st causes ~~a biohazardous~~ medical waste to become subject to regulation.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(17) "Hazardous waste"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following citation be changed:

"Hazardous waste" has the meaning prescribed in A.R.S. § 49-921~~(5).~~

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(25) "Infectious agent"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

~~25. "Infectious agent" means a type of microorganism, bacteria, mold, parasite, or virus that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.~~

ANALYSIS & RESPONSE: ADEQ has agreed to delete this definition.

R18-13-1401(33) "Tracking document"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

"Tracking document" means the written instrument ~~which~~ that signifies acceptance of biohazardous medical waste by a transporter, or a transfer, storage, treatment, or disposal facility operator.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(39) "Treatment certification"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

"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.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1401(41) "Universal biohazard symbol"

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

"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.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1402(A)(1)

ISSUE: GRRC staff requested for clarity, conciseness and understanding that the following be changed:

1. A generator who treats biohazardous medical waste on-site, before disposing of it as treated medical waste, and to any equipment used for that purpose. ~~A generator who treats on-site shall meet the requirements in R18-13-1405.~~ Specific requirements for a generator who treats on site are prescribed in R18-13-1405.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1402(A)(2)

ISSUE: GRRC staff requested for clarity, conciseness and understanding that the following sentence be changed:

2. A generator who contracts with a medical waste treatment facility for the purpose of treating biohazardous medical waste. ~~This generator shall meet the requirements of R18-13-1406.~~ Specific requirements for such a generator are prescribed in R18-13-1406.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1403(B)(5)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

5. A ~~public~~ health care worker who uses a multi-purpose vehicle in the conduct of routine business other than transporting waste, is exempt from the requirements of R18-13-1409 if the health care worker complies with all of the following:
   a. Packages the biohazardous medical waste according to R18-13-1407.
   b. Secures the packaged biohazardous medical waste within the vehicle so as to minimize spills.
   c. Transports the biohazardous medical waste to the ~~agency's central collection site~~ place of business or to a medical waste treatment or disposal facility.
   d. Cleans the vehicle when it shows visible signs of contamination.
   e. Secures the vehicle to prevent unauthorized contact with the biohazardous medical waste.

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1403(C)(1)

ISSUE: GRRC staff requested for clarity, conciseness, and understanding that the following sentence be changed:

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

1. A generator who treats biohazardous medical waste on-site and who accepts for treatment medical waste described in R18-13-1403(A)(4) is exempt from the requirement to obtain solid waste facility plan approval ~~described~~ prescribed in R18-13-1410.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1403(C)(4)

ISSUE: The GRRC staff identified an inconsistency with a total exemption of a person in possession of radioactive waste in R18-13-1403(A)(2) and a partial exemption of that same person in R18-13-1403(C)(4).

ANALYSIS: ADEQ agrees there is an inconsistency, and deletes R18-13-1403(C)(3).

R18-13-1404(B)

ISSUE: GRRC staff requested for clarity, conciseness and understanding that the following be changed**:**

B. A person who provides alternative medical waste treatment technology ~~in operation~~ 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 ~~described~~ prescribed in R18-13-1414 within 90 days after the effective date of this Article.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1404(B)(2)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

~~2. After 90 days of the effective date of this Article, not provide alternative medical waste treatment technology to additional generators until Departmental registration is received~~.

ANALYSIS: ADEQ has agreed to make this change.

RESPONSE: The rule now reads:

2. Not provide alternative technology 90 days after the effective date of this Article unless a Departmental registration certificate is received.

R18-13-1404(B)(3)

ISSUE: GRRC staff requested for clarity, conciseness and understanding, the following be changed:

3. After receipt of the Departmental registration certificate ~~is received~~, provide to all generators using the alternative treatment technology a copy of the registration ~~certification~~ certificate and the alternative technology manufacturer's specifications. ~~as required in R18-13-1414~~.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1404(C)

ISSUE: GRRC staff requested that for clarity, conciseness and understanding, the following be changed:

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, ~~as~~ 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 ~~is considered to be~~ as untreated biohazardous medical waste.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change. It had previously substituted the word "biohazardous" for the word "regulated."

R18-13-1404(E)

ISSUE: GRRC staff requested that for clarity and conciseness, the following sentence be changed:

E. A transporter of ~~regulated~~ biohazardous medical waste ~~before~~ 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).

ANALYSIS & RESPONSE: ADEQ has agreed to make this change. It had previously substituted the word "biohazardous" for the word "regulated."

The rule text now reads:

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).

R18-13-1404(F)

ISSUE: GRRC staff requested that for clarity and conciseness, the following sentence be changed:

F. An operator of a medical waste storage facility, who has obtained approval ~~as~~ for a solid waste facility ~~as described by~~ under A.R.S. § 49-762.04 ~~and who has obtained that approval~~ on or before the effective date of this Article, may continue

to store ~~regulated~~ biohazardous medical waste if the facility complies with the design and operation standards ~~described~~ prescribed in R18-13-1411. The addition of a refrigeration unit is a Type II change as described in R18-13-1413(A)(2).

ANALYSIS & RESPONSE: ADEQ has agreed to make this change. It had previously substituted the word "biohazardous" for the word "regulated" and corrected the citation to A.R.S. § 49-762.04.

R18-13-1404(G)

ISSUE: GRRC staff requested that for clarity and conciseness, the following sentence be changed:

G. An operator of a medical waste transfer facility ~~must~~ 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.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1404(H)

ISSUE: GRRC staff requested that for clarity and conciseness, the following sentence be changed:

H. An operator of a medical waste treatment facility who has obtained Departmental plan approval to operate a medical waste treatment facility ~~and who has obtained that approval~~ 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 paragraph below.
2. If the treater determines that the waste is not being treated to the applicable treatment standards of R18-13-1415, the treater ~~shall inform~~ informs the Department within 2 working days ~~of this~~ after the date on the determination, and within 30 working days ~~enter~~ enters into an administrative consent order to bring the facility into compliance.

ANALYSIS & RESPONSE: ADEQ has agreed to make these changes.

R18-13-1404(J)

ISSUE: GRRC staff requested that for clarity and conciseness, the following sentence be changed:

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 ~~receiving~~ the date on the Department's determination. The treater may continue to operate under the conditions specified in subsection ~~(F)~~ (H) of this Section while the Department reviews and determines whether to approve or deny the updated plan.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1405(A)

ISSUE: GRRC staff requested that for clarity and conciseness, the following sentence be changed:

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

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-1405(B)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following citations be corrected: B.A generator who uses:

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

ANALYSIS & RESPONSE: ADEQ has agreed to make this correction.

R18-13-1405(C)

ISSUE: GRRC staff requested that for clarity and conciseness, the following be changed:

C. A generator who incinerates biohazardous medical waste on site shall comply with all of the following ~~conditions~~ requirements:

1. Obtain a permit if required by the local or state air quality agency having jurisdiction.
2. Reduce the biohazardous medical waste, excluding metallic items, into carbonized or mineralized ash.
3. ~~Perform a waste determination of~~ Determine whether incinerator ash is hazardous waste as required by hazardous waste rules ~~adopted~~ promulgated under A.R.S. Title 49, Chapter 5.
4. Dispose of the non-hazardous waste incinerator ash at a Department-approved municipal solid waste landfill.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1405(E)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

E. A generator who uses an alternative treatment method on-site shall comply with all of the following ~~conditions~~:requirements:

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

ANALYSIS & RESPONSE: ADEQ agreed to make this change.

R18-13-1405(G)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

G. ~~Medical~~ A generator of medical sharps shall ~~be handled as described~~ shall handle medical sharps as prescribed in R18-13-1419.

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1407(C)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1409(B)

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

B. Upon receiving all of the following information from a transporter, the Department shall issue the registration after assigning a registration number to the transporter:

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 ~~an~~ a written acknowledgment that this disclosure is not required.
5. Photocopies or other evidence of the issuance of a permit, license, or approval ~~where~~ if required by a local health department, environmental agency, or other governmental agency with jurisdiction. ~~as described in subsection (A).~~
6. A copy of the transportation management plan required in subsection (C).

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

R18-13-1413

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

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

B. As required by A.R.S. § 49-762.06, a treatment facility operator who has identified ~~the~~ a change ~~as described in~~ under subsection (A) shall comply with ~~one~~1 of the following:
1. For a Type I change, make the change without notice to, or approval by the Department.
2. For a Type II change, before making any change, provide written notification that describes the change to the Department. The addition of refrigeration units only for compliance with this Article is a Type II change for which no Departmental approval is required.
3. For a Type III or Type IV change, submit an amended plan to the Department for approval before making any change. Departmental approval is required prior to making any change.

R18-13-1416. Recycled Materials

ISSUE: GRRC staff requested that for clarity, conciseness, and understanding the following be changed:

A. Once a generator places biohazardous medical waste in a red bag as required in R18-13-1407, ~~no one~~ a person shall not remove any of the biohazardous medical waste from the bag until the biohazardous medical waste has been treated as required in R18-13-1415.

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

ANALYSIS & RESPONSE: ADEQ has agreed to make this change.

CLARIFICATION CHANGE MADE BY ADEQ POST GRRC SUBMITTAL

ISSUE: Does the 2nd sentence of R18-13-1403(A)(4) in effect take away the exemption granted to a person by the 1st sentence? As submitted to GRRC the provision read:
A household generator residing in a private, public, or semi-public residence who generates biohazardous medical waste in the administration of self care or the agent of the household generator who administers the medical care. This exemption does not apply to a person residing in a facility licensed by the Arizona Department of Health Services.

ANALYSIS: ADEQ agrees that the wording may result in confusion. However, where any violation occurs, ADEQ intends to enforce against the owner/operator of the licensed facility, and not against individual patients. The intent of the provision was to make clear that exempt persons cannot "transfer" their exemption to a licensed facility.

RESPONSE: The rule now reads:
A household generator residing in a private, public, or semi-public residence who generates biohazardous medical waste in the administration of self care or the agent of the household generator who administers the medical care. This exemption does not apply to the facility in which the person resides if that facility is licensed by the Arizona Department of Health Services.

CHANGE MADE BY ADEQ POST GRRC SUBMITTAL

ISSUE: As submitted to GRRC on 5/7/99, R18-13-1415(A) and (B) read:

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

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

However, in its final review of the rule text, the Department of Health Services (ADHS) recommends that the original, proposed language "ensure that treatment achieves either of the following treatment standards" be substituted.

In its advice, ADHS states: "After review of the scientific literature and consulting with experts recently retired from the Hospital Infection Branch at the Centers for Disease Control and Prevention, the Department of Health Services does not recommend that inactivation of both *Mycobacteriae* and *Bacillus spp.* are necessary to demonstrate the treatment standard (high level disinfection). Conditions sufficient to inactivate *Bacillus* endospores will necessarily inactivate *Mycobacteriae.* The Department of Health Services strongly recommends changing R18-13-1415(A) to read, "A treater using an alternative treatment technology shall ensure that treatment achieves 1 of the following treatment standards:" and R18-13-1415(B) to read, "....through either of the following:"

ANALYSIS: As discussed in R18-13-1415 above, ADEQ made the original change on May 7, 1999 on the basis of advice given by an author of the Treatment Manual. ADEQ has since learned that there is a difference of scientific opinion on this issue and after consulting with ADHS has determined to follow that agency's advice. The end result of this is that the rule will now read as it was originally proposed in November of 1998.

RESPONSE: The rule now reads:

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

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

Additional changes for clarity, conciseness, and understanding were made to these rules at the suggestion of GRRC staff, but

are not shown in this section. All changes are shown in section 10.

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rule:

Not applicable

13. Incorporations by reference and their location in the rules:

29 CFR 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1998) is incorporated by reference in this rule in R18-13-1401(41). Copies of the incorporated material are available for inspection at the Department of Environmental Quality and the Office of the Secretary of State.

14. Was the rule previously adopted as an emergency rule?

No.

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

Sections

ARTICLE 14. BIOHAZARDOUS MEDICAL WASTE AND DISCARDED DRUGS

R18-13-1401. Definitions

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

1. "Administrative consent order" means a bilateral agreement between the consenting party and the Department. A bilateral agreement is not subject to administrative appeal.
2. "Alternative treatment technology" means a treatment method other than autoclaving or incineration, that achieves the treatment standards described in R18-13-1415.
3. "Approved medical waste facility plan" means the document that has been approved by the Department under A.R.S. § 49-762.04, and that authorizes the operator to accept biohazardous medical waste at its solid waste facility.
4. "Autoclaving," means using a combination of heat, steam, pressure, and time to achieve sterile conditions.
5. "Biohazardous medical waste" is composed of 1 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.

c. Human pathologic wastes: Discarded organs and body parts removed during surgery. Human pathologic wastes do not include the head or spinal column.
d. Medical sharps: Discarded sharps used in animal or human patient care, medical research, or clinical laboratories. This includes hypodermic needles; syringes; pipettes; scalpel blades; blood vials; needles attached to tubing; broken and unbroken glassware; and slides and coverslips.
e. Research animal wastes: Animal carcasses, body parts, and bedding of animals that have been infected with agents that produce, or may produce, human infection.

6. "Biologicals" means preparations made from living organisms or their products, including vaccines, cultures, or other biological products intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining to these activities.
7. "Biological indicator" means a representative microorganism used to evaluate treatment efficacy.
8. "Blood and blood products" means discarded human blood and any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived products.
9. "C.F.R." means the Code of Federal Regulations.
10. "Chemotherapy waste" means any discarded material that has come in contact with an agent that kills or prevents the reproduction of malignant cells.
11. "Dedicated vehicle" means a motor vehicle or trailer that is pulled by a motor vehicle used by a transporter for the sole purpose of transporting biohazardous medical waste.
12. "Discarded drug" means any prescription medicine, over-the-counter medicine, or controlled substance, used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to abandon. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.
13. "Disposal facility" means a municipal solid waste landfill that has been approved by the Department under A.R.S. § 49-762.04 to accept untreated biohazardous medical waste for disposal.
14. "Facility plan" has the meaning given to it in A.R.S. § 49-701.
15. "Free flowing" means liquid that separates readily from any portion of a biohazardous medical waste under ambient temperature and pressure.
16. "Generator" means a person whose act or process produces biohazardous medical waste, or a discarded drug, or whose act 1st causes medical waste or a discarded drug to become subject to regulation.
17. "Hazardous waste" has the meaning prescribed in A.R.S. § 49-921.
18. "Health care worker" means, with respect to R18-13-1403(B)(5), a person who provides health care services at an off-site location that is none of the following: a residence, a facility where health care is normally provided, or a facility licensed by the Arizona Department of Health Services.
19. "Improper disposal of biohazardous medical waste" means the disposal by a person of untreated or inadequately treated biohazardous medical waste at any place that is not approved to accept untreated biohazardous medical waste.
20. "Independent testing laboratory" means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.
21. "Medical sharps container" means a vessel that is rigid, puncture resistant, leak proof, and equipped with a locking cap.
22. "Medical waste," as defined in A.R.S. § 49-701, means "*any solid waste which is generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biologicals, and includes discarded drugs but does not include hazardous waste as defined in A.R.S. § 49-921 other than conditionally exempt small quantity generator waste.*"
23. "Medical waste treatment facility" or "treatment facility" means a solid waste facility approved by the Department under A.R.S. § 49-762.04 to accept and treat biohazardous medical waste from off-site generators.
24. "Multi-purpose vehicle" means any motor vehicle operated by a health care worker, 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.
25. "Off site" means a location that does not fall within the definition of "on site" contained in A.R.S. § 49-701.
26. "Packaging" or "properly packaged" means the use of a container or a practice under R18-13-1407.
27. "Putrescible waste" means waste materials capable of being decomposed rapidly by microorganisms.
28. "Radioactive material" has the meaning under A.R.S. § 30-651.
29. "Secure" means to lock out or otherwise restrict access to unauthorized personnel.
30. "Spill" means either of the following:
    a. Any release of biohazardous medical waste from its package while in the generator's storage area.
    b. Any release of biohazardous medical waste from its package or the release of packaged biohazardous medical waste by the transporter at a place or site that is not a medical waste treatment or disposal facility.
31. "Store" or "storage" means, in addition to the meaning under A.R.S. § 49-701, either of the following:

a. The temporary holding of properly packaged biohazardous medical waste by a generator in a designated accumulation area awaiting collection by a transporter.
b. The temporary holding of properly packaged biohazardous medical waste by a transporter or a treater at an approved medical waste storage facility or treatment facility.

32. "Technology provider" means a person that manufactures, or a vendor who supplies alternative medical waste treatment technology.
33. "Tracking document" means the written instrument that signifies acceptance of biohazardous medical waste by a transporter, or a transfer, storage, treatment, or disposal facility operator.
34. "Transportation management plan" means the transporter's written plan consisting of both of the following:
    a. The procedures used by the transporter to minimize the exposure to employees and the general public to biohazardous medical waste throughout the process of collecting, transporting, and handling.
    b. The emergency procedures used by the transporter for handling spills or accidents.
35. "Transporter" means a person engaged in the hauling of biohazardous medical waste from the point of generation to a Department-approved storage facility or to a Department-approved treatment or disposal facility.
36. "Treat" or "treatment" means, with respect to the methods used to render biohazardous medical waste less infectious: incinerating, autoclaving, or using the alternative treatment technologies prescribed in this Article.
37. "Treated medical waste" means biohazardous medical waste that has been treated and that meets the treatment standards of R18-13-1415. Treated medical waste that requires no further processing is considered solid waste.
38. "Treater" means a person, also known as an operator, who receives solid waste facility plan approval for the purpose of operating a medical waste treatment facility to treat biohazardous medical waste that is generated off site.
39. "Treatment certification statement" means the written document provided by either a generator who treats biohazardous medical waste on site or by a treater, to inform a solid waste disposal or recycling facility that biohazardous medical waste has been treated as prescribed in this Article, and therefore is no longer subject to regulation under this Article.
40. "Treatment standards" mean the levels of microbial inactivation, prescribed in R18-13-1415, to be achieved for a specific type of biohazardous medical waste.
41. "Universal biohazard symbol" or "biohazard symbol" means a representation that conforms to the design shown in 29 CFR 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1998) and which is incorporated by reference in this rule. This incorporation does not include any later amendments or editions. Copies of the incorporated material are available for inspection at the Department of Environmental Quality and the Office of the Secretary of State.
42. "Vehicle not dedicated to the transportation of biohazardous medical waste but which is engaged in commerce" means a motor vehicle or a trailer pulled by a motor vehicle whose primary purpose is the transporting of goods that are not solid waste or biohazardous medical waste and that is used by a transporter for the temporary transportation of biohazardous medical waste.

R18-13-1402. Applicability

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

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

R18-13-1403. Exemptions; Partial Exemptions

A. The following persons are exempt from the requirements of this Article:
1. Law enforcement personnel handling biohazardous medical waste for law enforcement purposes.

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

B. The following are conditionally exempt from the requirements of this Article:
1. A person who prepares human corpses, remains, and anatomical parts that are intended for interment or cremation. However, if medical sharps are generated during the preparation of the human remains, they must be disposed of as prescribed by this Article.
2. A person who operates an emergency rescue vehicle, an ambulance, or a blood service collection vehicle 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 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 business other than transporting waste, is exempt from the requirements of R18-13-1409 if the health care worker complies with all of the following:
   a. Packages the biohazardous medical waste according to R18-13-1407.
   b. Secures the packaged biohazardous medical waste within the vehicle so as to minimize spills.
   c. Transports the biohazardous medical waste to the place of business or to a medical waste treatment or disposal facility.
   d. Cleans the vehicle when it shows visible signs of contamination.
   e. Secures the vehicle to prevent unauthorized contact with the biohazardous medical waste.
6. A person who transports biohazardous medical waste between multiple properties separated by a public thoroughfare and which is owned or operated by the same owner or governmental entity is exempt from the requirements of R18-13-1409 if the person complies with R18-13-1403(B)(5)(a)-(e).
7. A hospital that chooses to accept medical sharps from staff physicians who generate medical sharps in a private practice is exempt from the requirement to obtain facility plan approval as long as the hospital collects medical sharps for off-site treatment or disposal.

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

R18-13-1404. Transition and Compliance Dates

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 on-site 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 on-site 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 store biohazardous medical waste if the facility complies 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 2 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.

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

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

B. A generator who uses:

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

C. A generator who incinerates biohazardous medical waste on site shall comply with all of the following requirements:

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

D. A generator who autoclaves biohazardous medical waste on site shall comply with all of the following requirements:

1. Further process by grinding, shredding, or any other process, any recognizable animals and human tissue, organs, or body parts, to render such waste non-recognizable and ensure effective treatment.
2. Operate the autoclave at the manufacturer's specifications appropriate for the quantity and density of the load.
3. Keep records of operational performance levels for 6 months after each treatment cycle. Operational performance level recordkeeping includes all of the following:
   a. Duration of time for each treatment cycle.
   b. The temperature and pressure maintained in the treatment unit during each cycle.
   c. The method used to determine treatment parameters in the manufacturer's specifications.
   d. The method in manufacturer's specifications used to confirm microbial inactivation and the test results.
   e. Any other operating parameters in the manufacturer's specifications for each treatment cycle.
4. Keep records of equipment maintenance for the duration of equipment use that include the date and result of all equipment calibration and maintenance.

E. A generator who uses an alternative treatment method on site shall comply with all of the following requirements:

1. Use only alternative treatment methods registered under R18-13-1414.

2. Further process by grinding, shredding, or any other process, any recognizable animals and human tissue, organs, or body parts, to render this waste non-recognizable and ensure effective treatment.
3. Follow the manufacturer's specifications for equipment operation.
4. Supply upon request all of the following:
   a. The Departmental registration number for the alternative medical waste treatment technology and the type of biohazardous medical waste that the equipment is registered to treat.
   b. The equipment specifications that include all of the following:
      i. The operating procedures for the equipment that enable the treater to comply with the treatment standards described in this Article for the type of waste treated.
      ii. The instructions for equipment maintenance, testing, and calibration that enable the treater to comply with the treatment standards described in this Article for the type of waste treated.
5. Maintain a training manual regarding the proper operation of the equipment.
6. Maintain a treatment record consisting of a log of the volume of medical waste treated and a schedule of calibration and maintenance performed under the manufacturer's specifications.
7. Maintain treatment records for 6 months after the treatment date for each load treated.
8. Maintain the equipment specifications for the duration of equipment use.

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

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

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

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

A. A generator of biohazardous medical waste shall package the waste as prescribed in R18-13-1407 before self-hauling or before setting the waste out for collection by a transporter.

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 1 year from the date of acceptance by the transporter. The tracking document shall contain all of the following information:
1. Name and address of the generator, transporter, and medical waste treatment, storage, transfer, or disposal facility, as applicable.
2. Quantity of biohazardous medical waste collected by weight, volume, or number of containers.
3. Identification number attached to bags or containers.
4. Date the biohazardous medical waste is collected.

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

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

R18-13-1407. Packaging

A. A generator who sets biohazardous medical waste out for collection for off-site treatment or disposal shall package the biohazardous medical waste in either of the following:
1. A red disposable plastic bag that is:
   a. Leak resistant,
   b. Impervious to moisture,
   c. Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling,
   d. Sealed to prevent leakage during transport,
   e. Puncture resistant for sharps, and
   f. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and bear the universal biohazard symbol. The secondary container may be either disposable or reusable.
2. A reusable container that bears the universal biohazard symbol and that is:
   a. Leak-proof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water, and

b. Used for the storage or transport of biohazardous medical waste and cleaned after each use unless the inner surfaces of the container have been protected by disposable liners, bags, or other devices removed with the waste. "Cleaning" means agitation to remove visible particles combined with 1 of the following:
   i. Exposure to hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.
   ii. Exposure to an EPA-approved chemical disinfectant used under established protocols and regulations.
   iii. Any other method that the Department determines is acceptable, if the determination of acceptability is made in advance of the cleaning.

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

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

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

R18-13-1408. Storage

A. A generator may place a container of biohazardous medical waste alongside a container of solid waste if the biohazardous medical waste is identified and not allowed to co-mingle with the solid waste. The storage area shall not be used to store substances for human consumption or for medical supplies.

B. Once biohazardous medical waste has been packaged for shipment off site, a generator shall provide a storage area for biohazardous medical waste until the waste is collected and shall comply with both of the following requirements:
1. Secure the storage area in a manner that restricts access to, or contact with the biohazardous medical waste to authorized persons.
2. Display the universal biohazard symbol and post warning signs worded as follows for medical waste storage areas: (in English) "CAUTION -- BIOHAZARDOUS MEDICAL WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and (in Spanish) "PRECAUCION -- ZONA DE ALMACENAMIENTO DE DESPERDICIOS BIOLOGICOS PELIGROSOS -- PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS."

C. Beginning at the time the waste is set out for collection, a generator who stores biohazardous medical waste shall comply with all of the following requirements:
1. Keep putrescible biohazardous medical waste unrefrigerated if it does not create a nuisance. However, refrigerate at 40° F. or less putrescible biohazardous medical waste kept more than 7 days.
2. 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. Keep the storage area free of visible contamination.
4. 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. 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. Notwithstanding subsection (C)(1), if odors become a problem, a generator shall minimize objectionable odors and the off-site migration of odors. If the Department determines that a generator has not acted or adequately addressed the problem, the Department shall require the waste to be removed or refrigerated at 40° F or less.

R18-13-1409. Transportation

A. A transporter shall register with the Department 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. Upon receiving all of the following information from a transporter, the Department shall issue the registration after assigning a registration number to the transporter:
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 required in subsection (C).

C. 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.

D. A transporter who accepts biohazardous medical waste from a generator shall leave a 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.

E. A transporter who transports biohazardous medical waste in a vehicle dedicated to the transportation of biohazardous medical waste shall ensure that the cargo compartment can be secured to limit access to authorized persons at all times except during loading and unloading. In addition, the cargo compartment shall be constructed in compliance with 1 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.

F. 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, shall comply with the following:

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

G. A person who transports 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 as prescribed in R18-13-1406(B), and keep a copy of the tracking document for 1 year.
3. Deliver biohazardous medical waste to a Department-approved biohazardous medical waste storage, transfer, treatment, or disposal facility within 24 hours of collection or refrigerate the waste for not more than 90 days at 40° F. or less until delivery.
4. Not hold biohazardous medical waste longer than 96 hours in a refrigerated vehicle unless the vehicle is parked at a Department-approved facility.
5. 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.

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

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

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

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

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

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

1. Design the facility so that biohazardous medical waste is always handled and stored separately from other types of solid waste if accepted at the facility.
2. Display prominently the universal biohazard symbol as prescribed in R18-13-1401.
3. Construct the storage area from smooth, easily cleanable non-porous material that is impervious to liquids and resistant to corrosion by disinfecting agents and hot water.
4. Protect biohazardous medical waste from contact with water, precipitation, wind, or animals.
5. Specify in the application for facility plan approval the maximum storage time that biohazardous medical waste will remain at the facility. If the biohazardous medical waste will be stored for more than 24 hours, the operator shall equip the facility with a refrigerator to refrigerate the 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. The operator shall sign the tracking form and keep a copy of the acceptance documentation for 1 year;
7. Accept biohazardous medical waste if it is packaged as described in R18-13-1407. If a biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a transfer facility operator shall do 1 of the following:

a. Reject the waste and return it to the transporter.
b. Accept the waste and immediately repackage it as prescribed in R18-13-1407(A).

8. Clean the storage area daily as prescribed in R18-13-1407(A)(2).

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

A. An operator who applies for facility plan approval shall comply with all of the following:

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

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

B. As required by A.R.S. § 49-762.06, a treatment facility operator who has identified a change under subsection (A) shall comply with 1 of the following:
1. For a Type I change, make the change without notice to, or approval by the Department.
2. For a Type II change, before making any change, provide written notification that describes the change to the Department. The addition of refrigeration units only for compliance with this Article is a Type II change for which no Departmental approval is required.
3. For a Type III or Type IV change, submit an amended plan to the Department for approval before making any change. Departmental approval is required prior to making any change.

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

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

B. The Department shall make a determination whether to approve the registration application. If the Department approves the application, it shall issue to the applicant a certification of registration containing an alternative medical waste treat-

ment method registration number. Only an alternative technology method with a valid Department issued registration number meets the requirements of this Article.

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

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

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

C. A treater utilizing an alternative treatment method shall quantify microbial inactivation as follows:
1. Microbial inactivation, or "kill" efficacy is equated to "Log_{10} Kill" that is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment. This definition is stated as:
   $\text{Log}_{10}\text{Kill} = \text{Log}_{10}(\text{cfu/g "I"}) - \text{Log}_{10}(\text{cfu/g "R"})$
   where:
   Log_{10}Kill is equivalent to the term Log_{10} reduction,
   "I" is the number of viable test microorganisms introduced into the treatment unit,
   "R" is the number of viable test microorganisms recovered from the treatment unit, and
   "cfu/g" are colony forming units per gram of waste solids.
2. For those treatment processes that can maintain the integrity of the biological indicator carrier of the desired microbiological test strain, biological indicators of the required strain and concentration may be used to demonstrate microbial inactivation. Quantification is evaluated by growth or no growth of the cultured biological indicator.
3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator, quantitative measurement of microbial inactivation requires a 2-step approach: Step 1 "Control" and Step 2 "Test". The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.
   a. Step 1:
      i. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.
      ii. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the treatment agent (that is, heat, chemicals).
      iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
      iv. Plate the recovered microorganism suspensions to quantify microbial recovery. The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the treatment agent.
      v. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction, either a 6 Log_{10} reduction for vegetative microorganisms or a 4 Log_{10} reduction for bacterial spores. This can be defined by the following equation:
      $\text{Log}_{10}\text{RC} = \text{Log}_{10}\text{IC} - \text{Log}_{10}\text{NR}$
      or
      $\text{Log}_{10}\text{NR} = \text{Log}_{10}\text{IC} - \text{Log}_{10}\text{RC}$
      where:
      Log_{10}RC is greater than 6 for vegetative microorganisms and greater than 4 for bacterial spores and where:
      Log_{10}RC is the number of viable "control" microorganisms in colony forming units per gram of waste solids recovered in the non-treated, processed waste residue;
      Log_{10}IC is the number of viable "control" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit;
      Log_{10}NR is the number of "control" microorganisms in colony forming units per gram of waste solids which

were not recovered in the non-treated, processed waste residue. Log_{10}NR represents an accountability factor for microbial loss.

b. Step 2:
   i. Use microbial cultures of the same concentration as in Step 1.
   ii. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the treatment agent.
   iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
   iv. Plate recovered microorganism suspensions to quantify microbial recovery.
   v. From data collected from Step 1 and Step 2, the level of microbial inactivation, "Log_{10} Kill", is calculated by employing the following equation:
   $Log_{10}Kill = Log_{10}IT - Log_{10}NR - Log_{10}RT$
   where:
   Log_{10}Kill is equivalent to the term Log_{10} reduction;
   Log_{10}IT is the number of viable "Test" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit. $Log_{10}IT = Log_{10}IC$;
   Log_{10}NR is the number of "Control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated, processed waste residue;
   Log_{10}RT is the number of viable "Test" microorganisms in colony forming units per gram of waste solids recovered in treated, processed waste residue.

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

R18-13-1416. Recycled Materials

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

B. A generator of biohazardous medical waste intending to recycle any portion of the biohazardous medical waste shall segregate that portion of biohazardous medical waste from the portion of biohazardous medical waste that will not be recycled. The generator shall do either of the following:
1. Treat the biohazardous medical waste intended for recycling as required in R18-13-1415 before sending the treated medical waste to a recycler.
2. Follow the requirements in R18-13-1406, R18-13-1407, and R18-13-1408, before either contracting with a transporter to haul or self-hauling the biohazardous medical waste to a treatment facility for treatment. After treatment, the treated medical waste may be sent to a recycler.

R18-13-1417. Disposal Facilities: Operation

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

R18-13-1418. Discarded Drugs

A. A generator of discarded drugs not returned to the manufacturer shall destroy the drugs on site 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

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.
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.

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 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 secondary inner container that is then placed inside an 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 waste shall be incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
3. Experimental or research animal waste shall be handled as follows:
   a. Autoclave bedding on site or package as described in R18-13-1407 for off-site treatment or landfilling.
   b. Incinerate animal carcasses on site, or if taken off site for treatment, comply with 1 of the following requirements:
      i. Package the waste in a leakproof, covered container, label the contents and send to an incinerator or a Department-approved landfill, or
      ii. If treated by a method other than incineration, pre-process by grinding, then treat by a method that achieves the standards of R18-13-1415(A).

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