

NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for Register publication and filing and the agency decides that prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office. The Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 411001 et seq.) publication of the Notice of Supplemental Proposed Rulemaking in the Register before holding any oral proceedings (A.R.S. § 411022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY
SOLID WASTE MANAGEMENT

PREAMBLE

- Register citation and date for the original Notice of Proposed Rulemaking:**
2 A.A.R. 1671, May 10, 1996
- | Sections Affected: | Rulemaking Action |
|---------------------------|--------------------------|
| Article 14 | New Article |
| R18-13-1403 | New Section |
| R18-13-1415 | New Section |
| R18-13-1420 | New Section |
| R18-13-1421 | New Section |
| R18-13-1422 | New Section |
| R18-13-1423 | New Section |
| R18-13-1424 | New Section |
| R18-13-1425 | New Section |
- 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; 41-1022(D); and 49-104
Implementing statutes: A.R.S. §§ 49-761(A)(3); 49-761(B)(3); 49-761(B)(4); and 49-762.06
- The name and address of agency personnel with whom persons may communicate regarding the rule:**
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- An explanation of the rule, including the agency's reasons for initiating the rule:**
General Background for the rule:

Pursuant to A.R.S. § 49-761, this proposed rule sets forth handling, treatment, and disposal standards for biohazardous medical waste, which protects the environment and the health of regulated medical waste handlers and the public at large.

Infectious disease transmission is a chain of 4 events: the presence of an infectious agent; a sufficient number of infectious agents to cause an infection; a susceptible host, (a person who does not possess sufficient resistance to a particular infectious agent to prevent contracting a disease if exposed to it); and a portal of entry to the host, such as a break in the skin or an orifice. The purpose of the proposed rule is to set forth enforceable standards which, when met, break the chain of disease transmission.

A.R.S. § 49-761(A)(3) requires that the Department of Environmental Quality ("ADEQ" or "the Department") adopt rules regarding the regulation of biohazardous medical waste. A.R.S. § 49-761(B)(3) permits the Department to decide whether to impose additional regulatory requirements (beyond the existing solid waste requirements) upon non-biohazardous medical waste. The Department believes that non-biohazardous medical waste does not pose a risk significantly different to that of general solid waste, unlike biohazardous medical waste. Therefore, the Department generally believes that non-biohazardous medical waste is adequately regulated under the existing solid waste regulations. For this reason, the proposed rule sets forth handling and treatment standards for only biohazardous medical waste.

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Background for the substantive changes to the proposed rule.

In May 1996, the Department proposed rules for handling, treatment, and disposal of biohazardous medical waste. These rules included proper packaging and storage, and treatment standards which must be met in order for biohazardous medical waste to be rendered non-infectious, or solid waste. A comment period was held from May 10, 1996 (the date the Notice of Proposed Rule was published in the *Arizona Administrative Register*) to June 28, 1996. During that time the Department held 3 oral proceedings throughout the state.

The Department received 16 comment letters regarding the proposed rule. In considering the comments received, the Department determined that the rule should be changed to address issues raised in the comments. Certain of these changes constitute substantial change, as described in A.R.S. § 41-1025(B). Accordingly, this Notice of Supplemental Proposed Rulemaking is published in accordance with A.R.S. § 41-1022(D).

The Department receives calls on a daily basis from healthcare providers and interested citizens inquiring about the proper handling and disposal of biohazardous medical waste. In fact, many persons have communicated a sense of urgency that these safeguards are needed and that too much time has already elapsed without effective regulations. During the public comment period, the Department did not receive any comments or indications which make it doubt that there is general agreement about the serious need to promulgate these rules.

While there is general agreement that something must be done, there remain differences of opinion regarding which treatment standards provide acceptable protection. This is so despite 3 round table discussions that the Department held prior to proposing the rule on May 10, 1996. These differences of opinion arise from differing scientific opinions of the degree of risk posed by biohazardous medical waste.

The Department further recognizes that many medical waste treatment interests are competing for a market share of the waste that is required to be treated by this rule. Not only is there an economic interest in what is required to be treated (i.e., how much is defined as biohazardous medical waste), there is an economic interest in the treatment level as certain treatment interests are capable of achieving a more stringent standard (such as sterilization) than others.

This rule has been developed with these contradictory forces in mind -- the difference of opinion over the risk actually posed by biohazardous medical waste, and the Department's knowledge of the economic competition for market share. In light of this, the Department has determined that its appropriate regulatory role is to set the minimum standards the Department believes are protective of human health and the environment. In addition, the Department has taken the position that the rule should, in so far as possible, remain "market neutral" for all medical waste treatment interests which meet the minimum standard, and not serve to economically benefit some treatment interests over others.

Generators outside the greater Phoenix metropolitan area, and small generators overall expressed concern about the cost and accessibility of traditional medical waste treatment technology for rural, and for small quantity generators. At the round tables, the use of alternative medical waste treatment methods was agreed upon by participants as a means of lessening the economic and logistical treatment burden on these generators. The Department's position of remaining "market neutral" to allow alternative medical waste treatment technologies which meet the treatment standards to enter the Arizona market is consistent with this discussion.

The Department believes that a local jurisdiction has authority to impose additional requirements upon municipal landfill acceptance of medical waste as long as the jurisdiction provides for the proper disposal of solid waste as required by A.R.S. § 49-741. Stated another way, the Department reads A.R.S. § 49-704 as granting this flexibility so long as the requirements of A.R.S. § 49-741 are met.

The Department believes that the rule is protective of human health and the environment. But it is also aware of the split of opinion in Arizona (and nationwide) regarding the actual risk involved, and of the liability concerns of local landfills. The Department views its position as balancing its regulatory interest in setting state-wide protective standards with a local jurisdiction's ability to respond to more specific concerns.

In general, the Department has not deviated from its position that the high disinfection (the reduction of microbial life to levels at which infection is not likely) treatment level provides adequate protection of human health and the environment. While there is no consensus among states as to the appropriate standard, several other states have adopted the approach found in Arizona's proposed rule. At the same time, it is persuaded by comments received that sterilization is appropriate for cultures and stocks and that incineration is appropriate for chemotherapy waste. For that reason, these changes have been made to the treatment standards for these 2 types of waste as described below.

The final adopted rule will contain all of the changes made to the proposed rule. Today's Notice of Supplemental Proposed Rulemaking contains only substantial changes. It does not include non-substantial changes. The Department intends to make a response to all comments in the final concise explanatory statement ("CES") at the time of rule adoption. That CES will contain all rule changes, including changes which are not substantial. The Department believes that a final adopted rule which contains all changes, both substantive and non-substantive, is more comprehensible to the reader. For this reason, the Sections re-proposed today do not reflect all changes which will be made.

The Department received comments that the organization of the rule was confusing. For that reason, the final adopted rule will be re-organized. A reorganization was not attempted here, again because a final document reflecting all changes is more understandable. The Department does not consider reorganization to be a substantial change in light of A.R.S. § 49-1025.

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6. **An explanation of the substantial changes which resulted in this supplemental notice:**

Under A.R.S. § 41-1025, there are 3 kinds of change which are recognized as substantial: a change in the class of persons regulated, a change in the subject matter regulated, and whether the extent to which the effects of the adopted rule differ from the effects of the proposed rule. Applying these provisions, there are 8 substantial changes which are included in this supplemental notice.

Exemption of household generated medical waste. As proposed, biohazardous medical waste generated in a private, public, or semi-public residence was exempted from the requirements of the rule. Many comments were received regarding the proposed exemption of household generated medical waste. Some commenters stated that no exemption should be allowed, while others stated that the exemption should be narrowed. Comments were also received which favored the exemption as proposed. After careful consideration, the Department has decided to more narrowly define the exemption thus reducing the amount of biohazardous medical waste in the municipal solid waste stream. The Department responds to commenters who voiced concern that home generated medical waste is increasing in volume and that steps should be taken where possible to reduce the amount of biohazardous medical waste in the municipal solid waste stream.

Today's supplemental notice restricts that exemption to biohazardous medical waste resulting from self-administered care. Biohazardous medical waste generated in a facility licensed by the Department of Health Services, and biohazardous medical waste resulting from care provided by an agent, employee, or contractor of a home health care agency licensed by the Department of Health Services must be handled in accordance with the rulemaking.

The effect of the rulemaking is that home health care professionals whose services result in biohazardous medical waste are now responsible for removing that waste from private, public, or semi-public residences and treating it. The Department finds that this change, which regulates home health care professionals not formerly on notice of regulation, is a change in persons affected by the rule as set forth in A.R.S. § 41-1025(B)(1). In addition, waste which results from care provided by a home health care professional is now regulated, and this constitutes a change in subject matter as set forth in A.R.S. § 41-1025(B)(2).

While home health care professionals are required to remove biohazardous medical waste from the home and properly treat it, they do not become subject to other rule provisions as long as certain requirements are met. Under proposed R18-13-1413(B), a multi-purpose vehicle used by health personnel in the conduct of routine business is exempt from the requirements of the rule as long as the waste is properly packaged, the waste is contained within a separate container in the vehicle and kept decontaminated, and the biohazardous medical waste is transported to a treatment facility for treatment.

Exemption of waste deposited in a sanitary sewer system. The proposed rule allowed discharge of biohazardous medical waste to a sanitary sewer if performed under authority of the local waste water treatment facility in compliance with federal and local permit conditions pursuant to 40 CFR 460.12. Today's change restricts that allowable discharge by prohibiting the discharge of cultures and stocks, and otherwise limiting the allowable discharge to liquid and semi-liquid biohazardous medical waste. This change is consistent with the Department's response to concerns that cultures and stocks, because of their concentrated nature, represent a higher risk of infection than other categories of biohazardous medical waste. As noted elsewhere in the rulemaking, the Department now requires that this category of waste be subject to a higher treatment standard (sterilization) than is required for other categories of biohazardous medical waste. It is consistent, therefore, with this higher standard, to prohibit cultures and stocks from being disposed of by being flushed into a sanitary sewer.

This change in the allowable exemptions constitutes a change in subject matter as described in A.R.S. § 41-1025(B)(2). By restricting this exemption, the Department has now regulated subject matter not previously envisioned in the proposed rule.

Labeling of medical waste treated on-site. Under the proposed rule, there was no requirement that biohazardous medical waste treated on-site be labeled as treated medical waste. Commenters representing municipal landfills expressed concern that there is no way for a landfill operator or refuse collector to determine if small quantities of medical waste that are mixed with the general waste stream comply with the rule provisions. As a practical matter, the landfill operator or refuse collector may not be able to determine if waste from a dumpster is waste not regulated by this rule, or if it is regulated waste, whether it has been properly treated. In response to this comment, the Department now proposes to require that a generator who treats biohazardous medical waste on-site by a method other than incineration shall attach a label, placard, or tag with the following words: "This medical waste has been treated in accordance with the Arizona Department of Environmental Quality standards" to the bag or container prior to landfill disposal.

Similar to the change described above, this constitutes a change in subject matter as described in A.R.S. § 41-1025(B)(2). With the requirement, the Department has now regulated subject matter not previously envisioned in the proposed rule.

Chemotherapy waste. Chemotherapy waste was not singled out in the proposed rule for special handling. Several commenters have advised the Department that, although chemotherapy waste is not considered as an infectious biohazardous waste, it is often inappropriately incorporated into the hospital's biohazardous medical waste stream and for this reason should be addressed in the rule. Commenters suggested that due to its toxic nature, chemotherapy is chemically contaminated and requires high-temperature incineration. The Department has responded to these comments by requiring that chemotherapy waste be incinerated, or disposed of in an approved hazardous waste disposal facility.

This constitutes a change in subject matter as described in A.R.S. § 41-1025(B)(2). With the requirement, the Department has now placed a restriction on the treatment method for this waste not previously envisioned in the proposed rule.

Cultures and stocks. In the proposed rule, cultures and stocks were subject to the high disinfection level. The Department has received comments that this category of waste contains known human pathogens grown to high concentration for diagnostic or

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research purposes. Because of its high concentration this category represents a greater risk of infection and should be subject to a higher level of treatment. The Department responds to these concerns by requiring that cultures and stocks be sterilized. Adequate treatment under the rulemaking is autoclaving, incineration, or any alternative treatment methodology which achieves sterilization. Sterilization is the destruction of all forms of microbial life.

The effect of this change is similar to the effect of the chemotherapy change, in so far as it affects subject matter as described in A.R.S. § 41-1025(B)(2). With the requirement, the Department has now placed a restriction on treatment method for cultures and stocks not anticipated in the proposed rule.

Hazardous waste determination. Commenters noted that the proposed medical waste rule provisions improperly placed responsibility on the Department for making a hazardous waste determination of incinerator ash. This conflicts with state and federal law which makes waste determination a responsibility of the generator. The Department acknowledges its error and corrects it with the rulemaking. Arguably, there is no change in the class of persons regulated by the rulemaking since existing state and federal law still requires generators to make hazardous waste determinations. However, the Department includes this change in the Notice of Supplemental Proposed Rulemaking in order to be clear about the responsibility for waste determination.

Substantial changes to solid waste facility plans. A.R.S. § 49-762.06 has become effective since the medical waste rule was proposed. This recent legislation lists 4 categories of changes which may be made to approved solid waste facilities and amended plans. This purpose of adding R18-13-1423 in the rulemaking is to address changes made to approved medical waste facilities. This new Section establishes the criteria used in determining the category type of a proposed change to a solid waste facility handling biohazardous medical waste, and it sets forth the requirements which must be met in order to make these changes. The effect of adding this Section is to impose a burden on the treater who makes substantial changes to the approved plan. This regulatory burden relates to making changes to solid waste facility plans. The proposed rule did not envision changes to an approved plan, it simply required plan approval for solid waste facilities which handle biohazardous medical waste. This change constitutes a change in persons affected by the rule as set forth in A.R.S. § 41-1025(B)(1). This new Section also regulates subject matter (changes to solid waste facility plan approval) not previously anticipated, and as such it affects subject matter as described in A.R.S. § 41-1025(B)(2).

Responsibility for compliance with treatment standards. The Department received many comments that the proposed rule was unclear as to who bears the burden of demonstrating compliance with the treatment standards described in R18-13-1412. In response, the Department has revised the rule for clarity.

The 1st change in the proposed rule is a new R18-13-1424 which requires that manufacturers of alternative medical waste treatment methods must register with the Department and lists the material which is submitted with that registration. An alternative medical waste treatment method is a treatment method other than autoclaving and incineration.

This new Section also requires that the Department make its determination within 30 days after receiving an administratively complete application. Registration with the Department is a pre-requisite to use of any alternative medical waste treatment methods.

A 2nd change in this area is a new R18-13-1425 which sets forth requirements which must be met by generators who treat their waste on-site. This Section lists equipment documentation which must be kept for the life of the equipment, and requires that a treatment log be kept for 6 months. The treatment log lists the volume of medical waste treated and a schedule of equipment calibration and maintenance. The purpose of the treatment log is to provide a record which shows that the volume of waste treated does not exceed the equipment's operational capabilities.

The effect of adding R18-13-1424 is to impact subject matter as described in A.R.S. § 41-1025(B)(2). The new Section requires registration of alternative medical waste treatment methods, and registration was not previously required. This new Section also imposes a burden of registering with the Department on a new class of persons, manufacturers. Although presently it is common practice for manufacturers to send treatment equipment information and treatment efficacy information to the Department, under the new Section registration is required prior to equipment operation. Because registration is now mandatory and not voluntary, the effect of this change is to regulate manufacturers not formerly on notice of regulation. As such it is a change in persons affected by the rule as set forth in A.R.S. § 41-1025(B)(1).

The effect of adding R18-13-1425 is to require treaters who utilize alternative medical waste treatment methods to use only methods which are registered with the Department. Because under the proposed rule treaters utilizing alternative medical waste methods were not on notice of this requirement, this change impacts subject matter as described in A.R.S. § 41-1025(B)(2). Arguably, the requirement to keep treatment records in this Section is not a change in subject matter. As proposed, treaters were on notice to keep records of equipment maintenance and operational performance levels. However, the addition of R18-13-1425 makes clearer that treaters who treat their waste on-site are required to maintain these records.

7. 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.
8. The preliminary summary of the economic, small business, and consumer impact:
 - A. Identification of proposed rulemaking

This notice of supplemental proposed rulemaking contains substantial changes to the original proposed rulemaking entitled Medical Waste, 18 A.A.C. 13. The summary of this supplemental economic, small business, and consumer impact statement ("EIS") comprises the entire document, i.e., no additional material is included in the agency's rulemaking docket.

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B. Introduction

This EIS contains an assessment of the impacts of the 8 substantial changes made to the originally proposed rulemaking. While these changes are considered substantial in terms of requiring a supplemental notice, the economic burden to the entities affected does not appear to be substantial. The Department expects the supplemental rule only to have a modicum incremental effect on the original EIS. In monetary terms, these changes are expected to generate a minimal (\$18,000) to moderate (\$234,000) overall cost to the entities impacted. This range represents a minimal to a worst-case scenario, principally, for generators to comply with the supplemental rule. It was developed by summing all of the cost designators for generators shown in Table 1 and the expected cost range for entities other than generators.

Even though the Department expects the compliance burden to be small, the benefits are expected to exceed the costs. In fact, the overall cost, potentially, could be more towards the lower range. These benefits are expected to accrue across the board to both the health-care industry and the public at large. These potential benefits are expected to accrue over and above those benefits recognized in the original rulemaking.

Today's supplemental rule is expected to generate a trio of general benefits. Reducing public or occupational exposure to untreated, or improperly treated or handled, biohazardous medical waste is expected to contribute towards the goal of lessening the probability of occurrence of injury, infection, or communicable disease. Obviously, this is a "protective" rule benefit which the Department perceives as a hidden benefit of costs avoided due to the potential for noninjuries and a break in the chain of disease transmission. The public health implication is that lives may be saved. Other benefits of the supplemental rule are that it provides additional protection of the environment and aesthetics. Finally, a "compliance" benefit will ensure that generators who voluntarily treat their biohazardous medical waste now will continue to treat. These rules also should help to clarify standards and requirements of all entities of this regulated industry. The registration of alternative technology methods by manufacturers, for example, is expected to clarify the procedures and make it easier for generators to purchase and use such treatment technologies. In contrast, those generators who currently are not treating should begin to do so, and if they do not, the Department can take enforcement action against them.

In the original Notice of Proposed Rulemaking, the EIS identified various entities the Department expected to be impacted. That EIS also discussed research activities, and in particular, survey inferences made from the generator survey conducted in mid-1995. The Department concluded the major impact would be on generators currently not treating their biohazardous medical waste. This overall compliance burden for generators was estimated at \$350,000. This very small economic burden was based on a survey inference that 95% of the approximately 7,300 generators already were treating their biohazardous medical waste. However, that EIS contained a caveat that such a high treatment rate could be overstated due to several reasons (e.g., small sample size and non-response bias). If less than the inferred 95% of all generators currently were treating their biohazardous medical waste, the economic impact on generators naturally would increase. It is important to also point out that this treatment burden included managing (e.g., packaging, treating, and disposing) the entire biohazardous medical waste stream as a whole and not as separate types. The separate types of biohazardous medical waste, by definition, which comprise this waste stream include the following: cultures and stocks; waste human blood and blood products, pathological wastes; medical sharps; research animal waste; and isolation waste.

This discussion brings us to the assessment of the impacts of the 8 substantial changes made to the originally proposed rulemaking. For the purpose of examining the impact of the supplemental rule, these 8 areas of change have been grouped into 4 subdivisions: (1) Addition to generators regulated (limited inclusion of home health agencies); (2) Special handling of certain types of biohazardous medical waste; (3) New requirements for generators treating on-site; and (4) Other changes. Anticipated costs to generators are examined according to these subdivisions.

C. Cost findings by 4 subdivisions

The following Section explains anticipated costs of the supplemental rule by the 4 subdivisions previously mentioned. The proportion of the total biohazardous medical waste stream (estimated at 22.2 million lbs. annually) that these rule changes will affect may be viewed as "infinitesimal." Although the potential number of generators that will experience a compliance cost is unknown, the Department expects the actual number to be relatively minimal. This is because the Department expects the majority of generators to currently be in compliance with the supplemental rulemaking.

(1) Addition to generators regulated (limited inclusion of home health agencies).

Employment is growing in the various health-care industries, particularly in home care, nursing and personal care facilities, and others. Home health care is a vital component of comprehensive care, and it represents a less expensive mechanism to care for the elderly sick and others who do not need to be institutionalized. There is a growing concern that care givers employed by home health agencies should be professionally responsible for removing these biohazardous medical wastes and subsequently treating them so that they do not end up as untreated waste in the solid waste stream. Today's rule brings this category of generator into the regulatory umbrella. This non-exemption for home health agencies could mean higher costs to do business, which may or may not be passed on to their patients.

According to the 1995 generator survey, home health agencies were predicted to generate about 52,000 lbs. of biohazardous medical waste annually. This amount represents less than 3/10 of a percent of the total biohazardous medical waste projected to be produced by all generators in Arizona in 1995. Furthermore, inferences from that survey predicted about 50% of the 134 home health agencies would spend \$50 per month to treat an average amount of 32 pounds of biohazardous medical waste at an annual cost of \$40,200. The other 50% of home health agencies would transfer their biohazardous medical waste to another entity, such as a hospital, conceivably at not cost to them. Consultation with

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commercial treatment vendors validated this cost. However, because the sample size was so small, the inferences made by the Department are not considered statistically valid.

Upon further research, the Department determined that the impact on home health agencies may be greater than what the results revealed from the generator survey. However it is difficult to infer from the generator survey how much greater might be this impact. Since the management of this waste varies according to the policies of each home health agency, many variables are unknown. For example, it is unknown what proportion of biohazardous medical waste is presently left in the homes for the patients to dispose of in the solid waste stream. It is unknown what proportion of these home health agencies actually remove all biohazardous medical waste produced from their care giving activities. Furthermore, chemotherapy waste would have to be managed as a separate waste stream by each agency. Thus, all of the biohazardous medical waste produced would have to be properly packaged, segregated as applicable, and transported back to the office, or point of collection, for subsequent treatment and disposal.

(2.) Special handling of certain types of biohazardous medical waste.

Certain types of biohazardous medical waste that the supplemental rule seeks to regulate differently than originally proposed represent an unknown, but relatively small, proportion of the total biohazardous medical waste produced in Arizona. For instance, the supplemental rulemaking prohibits generators from discharging cultures and stocks into a sanitary sewer. It also requires this waste stream to be sterilized by either autoclaving or incinerating, and it prohibits generators from discharging medical wastes other than liquids or semi-liquids into a sanitary sewer. Finally, it requires generators to incinerate chemotherapy wastes or dispose of them in an approved hazardous waste disposal facility.

Upon further research, the Department estimated that each area of change for handling these biohazardous medical wastes would generate a minimal compliance cost. This is because it is believed that cultures and stocks currently are managed as a separate waste stream. This category consists of cultures and stocks of infectious agents and associated biologicals (microbiological waste). This waste stream also could include discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures. The sources can come from a variety of generators (e.g., medical, pathological, research, and industrial laboratories). Likewise, it is believed that in many cases chemotherapy waste is managed as a separate waste at the present time. The Department also believes that the disposal of biohazardous medical waste other than liquids and semi-liquids into a sanitary sewer is not a wide-spread practice. As a result, compliance costs are expected to accrue to those generators currently not meeting the standards prescribed in these proposed rule changes.

(3.) New requirements for generators treating on-site.

Generators who treat biohazardous medical waste on-site, whether using a traditional treatment method (e.g., autoclaving) or an alternative technology method, must identify the packaged waste as "treated waste." This can be accomplished by applying a label, tag, or placard. To provide an idea of how minimal this compliance cost would be, if 900 generators treated 1 bag per day, the collective cost for purchasing printed labels should be less than \$30,000 annually. In addition, generators using an alternative technology method must maintain records of the volume of biohazardous medical waste treated and records of calibration and maintenance performed in accordance with the manufacturers' specifications of such equipment. These records must be maintained for 6 months. The generators also must maintain on-site various written documentation.

(4.) Other changes

There are 2 changes in the "other changes" category. Neither are expected to create a compliance cost. The 1st 1 pertains to an error in the original rule proposal which improperly made the Department responsible for making a hazardous waste determination. Today's supplemental rule corrects this error. The other change pertains to solid waste facilities that would amend their solid waste plans. For example, a medical waste facility ("a commercial treatment vendor") which might make certain changes in its storage capacity or treatment equipment. Depending on the magnitude and type of change (types I-IV), the changes trigger a Department notification requirement, that may include a public notification. Since the supplemental rule actually creates a less stringent requirement for a Department notification for these facilities, the Department does not expect a compliance cost to result. However, this latter rule change does produce a benefit.

Incremental impact means probable costs and benefits that would occur as a result of implementing the changes proposed in the supplemental rule compared to the costs and benefits of the original proposed rule. Incremental impacts of these rule changes are comprised of these cost components: 1) treatment, 2) procedural, and 3) administrative. They are explained below.

Treatment impacts include costs to generators to treat their biohazardous medical waste either on-site or off-site, i.e., contracting with a commercial treatment vendor to transport their biohazardous medical waste off-site for subsequent treatment and disposal. It also may include the cost of purchasing red bags and containers. Procedural impacts include all costs as a result of necessary changes to waste handling protocols (e.g., segregating waste streams at points of origin and subsequent collection, storage, and disposal procedures) and monitoring. Finally, administrative impacts include all other management costs (e.g., recordkeeping, reporting, training, and applying labels). Table 1 shows estimated compliance costs of the supplemental rule on Arizona's generators.

Table 1. Anticipated incremental impacts of proposed rule changes on generators: disaggregated by cost components (treatment, procedural, and administrative)

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RULE CHANGE	TREATMENT	PROCEDURAL	ADMINISTRATIVE
1. Home health agencies must comply with applicable rule provisions (the major cost will be treating)	MINIMAL	de minimis	de minimis
2. Cultures and stocks must be sterilized (discharge to the sanitary sewer is prohibited)	MINIMAL	de minimis	de minimis
3. Discharge of biohazardous medical waste, other than liquids and semi-liquids, into the sanitary sewer is prohibited	MINIMAL	de minimis	de minimis

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<p>4. Chemotherapy wastes must be incinerated or disposed of in an approved hazardous waste disposal facility</p>	<p>MINIMAL</p>	<p>de minimis</p>	<p>de minimis</p>
<p>5. Biohazardous medical waste treated on-site must be labeled as "treated" prior to disposal</p>			<p>MINIMAL</p>
<p>6. Documentation must be kept for bio-waste treated on-site by an alternative treatment technology</p>			<p>de minimis - MINIMAL</p>

In this table, de minimis means < \$3,000, MINIMAL means \$3,000 - \$30,000, and MODERATE means \$30,000 - \$234,000.

D. Cost findings for entities other than generators

The Department expects compliance costs for entities other than generators, which potentially could be impacted by these changes, to be considerably less than for generators (\$3,000 - \$30,000). Note that not all of these entities could be impacted. Some may experience de minimis to minimal compliance costs, while others may experience no costs. Whether or not they actually experience a compliance cost, they may receive benefits. These entities are identified below.

1. Transporters, except home health agency personnel who would transport biohazardous medical waste back to the office.
2. Commercial treatment vendors which treat off-site, including companies that sell postal mail-back or encapsulating systems principally for medical sharps.
3. Manufacturers of traditional treatment equipment (e.g., autoclave) and alternative treatment technology methods.
4. Laboratories which will test alternative treatment technology methods.

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5. Political subdivisions operating landfills, wastewater treatment plants, or such entities which manage solid waste or which respond to cleanups or investigate complaints.
6. Private entities which operate a landfill or which manage solid waste.
7. Personnel of certain occupational groups of the health-care industry who could come into contact with biohazardous medical waste that is untreated or improperly treated or disposed of (e.g., sanitation workers, landfill personnel, maintenance and repair workers, and some personnel of wastewater treatment plants).
8. Public at large.
9. The Department as the implementing and enforcing agency of this rulemaking.

For manufacturers of alternative treatment technologies and the Department, the supplemental rule is expected to create a minimal administrative impact. For example, manufacturers will have to register and provide the Department with certain written documentation that the equipment is capable of meeting treatment standards. In addition, they must demonstrate treatment efficacy of the technology used by having the equipment tested by an independent laboratory and submit the original results of the testing to the Department. In return, the Department will acknowledge the results by replying to these manufacturers will a letter and a registration number.

E. Impact on small businesses

According to the generator survey conducted in mid-1995, approximately 3/4 of the respondents classified their business as a small business. Depending on the generator category, the proportion ranged from 18 - 100%. 40% of the home health agencies responded that they are classified as a small business. According to the Department of Health Services' listing of Medicare certified/state licensed home health agencies, published in June of 1995, 34% were non-profit agencies (e.g., hospitals), 7% were government, and 59% were proprietary (private). Of the 79 agencies that were classified as proprietary, about 40% were designated as corporate proprietary.

Although it is unknown which generators mainly will be impacted by the rule, it is likely that small businesses will be impacted the greatest. This is due not only to the survey conclusion that most generators would be classified as a small business, and hence, any change would impact them the most, but also to rule changes which specifically will impact small businesses, i.e., generators treating biohazardous medical waste on-site most likely will be small quantity generators and small businesses. On an individual generator basis, the Department expects the cost to be de minimis (\$0 to \$3,000). This includes the cost of an inexpensive, bench top autoclave for a small generator who wishes to treat biohazardous medical waste on-site.

To reduce the impact on small businesses, the supplemental rule did not mandate a specific treatment technology method. Likewise, these rule changes were designed to reduce costs on small businesses, and particularly the small generators. For example, not all biohazardous medical waste, except cultures and stocks, must be sterilized, and the discharge of liquid and semi-liquid waste into a sanitary sewer is not prohibited. Furthermore, only limited data must be maintained by the generator treating on-site using an alternative treatment technology method. Finally, generators are free to select a treatment option that will best suit their needs, whether it means treating on-site (using a traditional or alternative technology method), contracting with a commercial treatment vendor for off-site treatment, utilizing a postal mail-back system, or using a technology to encapsulate medical sharps.

F. Conclusion

The cost components shown in Table 1 are expected to create direct costs to the generators currently not meeting these proposed, supplemental rule standards. However, the Department does not expect these costs to be unreasonably burdensome to the health-care providers or the consumers of their services. Furthermore, any costs passed on from health-care providers to these consumers are expected to be minimal. These changes are not expected to impede the entry of alternative treatment technologies or to alter competition or market share. The Department does not anticipate an increased cost to the general public. This rule impacts the total population and not just consumers of health-care services.

Today's supplemental rule requires biohazardous medical waste to be managed in such a way that is protective of public health, safety, and the environment. It has the potential to reduce communicable diseases, reduce contact with infectious agents, reduce injuries from medical sharps, reduce incidents of improper disposal, and improve environmental and aesthetic quality. This is why the Department expects the benefits to outweigh the relative minimal costs of compliance. It is important to emphasize that the supplemental rule only makes changes that have a relatively small compliance impact and does not change the original cost-benefit analysis. The medical waste rule in general seeks to maximize net benefits to society.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: David Lillie
Address: Department of Environmental Quality
3033 North Central Ave. # 844
Phoenix, Arizona 85012-2809
Telephone: (602) 207-4436 or (800) 234-5677, ext. 4436 (AZ only)
Fax: (602) 207-2251

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10. The time, place and nature of the proceedings for the adoption, amendment or repeal of the rule, or, if no proceeding is scheduled, where, when and how persons may request an oral proceeding on the proposed rule:

Persons interested in submitting written comments on the proposed rules should mail or fax them to Katheryn A. Cross, identified above no later than 5 p.m. on January 17, 1997.

A series of public hearings have been scheduled to discuss the proposed rule and to receive public comments. They are scheduled for the following times and locations:

Date: January 6, 1997
Time: 1 p.m.
Location: Flagstaff City Council Chambers
211 West Aspen Avenue
Flagstaff, Arizona

Date: January 8, 1997
Time: 1 p.m.
Location: State Office Building
400 West Congress
Room #5, South Building
Tucson, Arizona

Date: January 10, 1997
Time: 1 p.m.
Location: ADEQ Public Meeting Room
3033 North Central Avenue
Phoenix, Arizona

The ADEQ is committed to complying with the Americans with Disabilities Act. If any individual with a disability needs any type of accommodation, please call (602) 207-4795 for special accommodations pursuant to the Americans with Disabilities Act. Persons interested in presenting verbal comments, submitting written comments, or obtaining more information on the proposed rules may do so at these meetings. The ADEQ will respond to all issues in the preamble accompanying the final rules.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
Not applicable.

12. Incorporation by reference and their location in the rules:

R18-13-1403(A)(5): 40 CFR 262.11

R18-13-1422(F)(2): 40 CFR 460.12

13. The full text of the rules follows:

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY

SOLID WASTE MANAGEMENT

ARTICLE 14. MEDICAL WASTE

- R18-13-1403. Exemptions
R18-13-1415. Disposal
R18-13-1420. Chemotherapy Waste
R18-13-1421. Cultures and Stocks
R18-13-1422. Medical Waste Treatment Facility: Design and Operational Requirements
R18-13-1423. Approved Medical Waste Treatment Facility Plans: Substantial Changes
R18-13-1424. Alternative Medical Waste Treatment Methods: Registration and Equipment Specifications.
R18-13-1425. Alternative Medical Waste Treatment Methods: Generators Who Treat Waste On-site

ARTICLE 14. MEDICAL WASTE

R18-13-1403. Exemptions

- A. The following are exempt from the requirements of this Article:
1. An individual residing in a private, public, or semi-public residence who generates biohazardous medical waste in the administration of self-care. This exemption does not apply to:
a. An individual residing in a facility licensed by the Department of Health Services;
b. An individual who uses the services of an agent, employee, or contractor of a home health care agency licensed by the Department of Health Services.
2. Human corpses, remains, and anatomical parts that are intended for interment or cremation.

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3. Source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2011 et. seq. (See R18-8-261(C)).
 4. Medical sharps, unused but not discarded, which are returned to the manufacturer via the U.S. Postal Service.
 5. Discharge of liquid and semi-liquid biohazardous medical wastes other than cultures and stocks to the sanitary sewer if performed under authority of the local waste water treatment facility in compliance with federal and local requirements pursuant to 40 CFR 460.12, as amended as of July 1, 1995. 40 CFR 460.12, as amended as of July 1, 1995. (and no future editions), is incorporated by reference and is on file with the Department of Environmental Quality and the Office of the Secretary of State.
 6. Hazardous waste subject to regulation under A.R.S. Title 49, Chapter 5, which is not conditionally exempt from hazardous waste requirements.
- B.** A multi-purpose vehicle used by health personnel in the conduct of routine business shall be exempt from the requirements of this Article if all of the following are met:
1. The biohazardous medical waste is packaged as described in R18-13-1407;
 2. The vehicle is equipped with compartments or other barriers, and biohazardous medical waste is contained within the compartment in a separate sealed rigid container;
 3. The container is decontaminated weekly and when it shows visible signs of contamination;
 4. The biohazardous medical waste is transported to a treatment facility for treatment.
- C.** A person who transports biohazardous medical waste between multiple properties owned or operated by the same owner or governmental entity shall be subject to the packaging requirements described in R18-13-1407. Receipt of biohazardous medical waste transported from 1 commonly owned or operated facility to another does not render the receiving facility a public facility as defined in this Article.

R18-13-1415. Disposal

- A.** Biohazardous medical waste treated by a method which achieves the treatment standards described in R18-13-1412 may be sent to a Department approved landfill or a recycling facility.
- B.** A generator who treats biohazardous medical waste on-site by a method other than incineration shall attach a label, placard, or tag with the following words: "This medical waste has been treated in accordance with the Department of Environmental Quality standards" to the bag or container prior to landfill disposal. The generator shall ensure that the label, placard, or tag is easily readable at a distance of 10 feet.
- C.** In the event of a public health emergency and with the written approval of the Department, untreated biohazardous medical waste may be placed in an approved municipal solid waste landfill if accepted by the landfill operator.

R18-13-1420. Chemotherapy Waste

A generator shall ensure that chemotherapy waste is incinerated or disposed of in an approved hazardous waste disposal facility.

R18-13-1421. Cultures and Stocks

A generator shall ensure that cultures and stocks are incinerated, steam sterilized, or treated by an alternative medical waste treatment method which achieves sterilization. Sterilization is the

destruction of all forms of microbial life.

R18-13-1422. Medical Waste Treatment Facility: Design and Operational Requirements

- A.** Any facility that is required to obtain plan approval under A.R.S. § 49-762 shall obtain plan approval from the Department prior to storing, transporting, transferring, treating, or disposing of biohazardous medical waste. In addition, a transfer facility shall comply with the requirements of subsection (B) and a treatment facility shall comply with the requirements of subsection (C). The approved facility plan shall set forth the maximum storage time biohazardous medical waste shall remain at the facility.
- B.** In addition to the requirements of subsection (A), a transfer facility may accept biohazardous medical waste if all of the following are met:
1. The facility stores biohazardous medical waste separate from other solid waste;
 2. The facility accepts biohazardous medical waste only if it is accompanied by the manifest described in R18-13-1411;
 3. The facility accepts biohazardous medical waste only if packaged as described in R18-13-1407. Where 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 generator,
 - b. Immediately repackage the waste in accordance with R18-13-1407.
 4. The facility stores biohazardous medical waste as described in R18-13-1408 except that biohazardous medical waste kept for longer than 24 hours shall be refrigerated;
 5. The facility delivers the biohazardous medical waste to a Department approved facility.
- C.** In addition to the requirements of subsection (A), a medical waste treatment facility may accept biohazardous medical waste if all of the following are met:
1. Written operating procedures maintained, including range and mean of time, temperature, and pressure, type of biohazardous medical waste accepted and treated, type of container, closure on container, pattern of loading, water content of waste, and maximum load quantity;
 2. Biohazardous medical waste is stored as described in R18-13-1408;
 3. Treatment standards are achieved as described in R18-13-1412;
 4. A management plan is maintained for the handling of hazardous chemicals, radioactive waste, and chemotherapy waste. The plan shall include an operating procedure that provides for scanning biohazardous medical waste with a Geiger counter and handling waste above background level in accordance with provisions of the plan approval. If there is no plan approval, radioactive waste above background level shall be handled in accordance with state and federal law;
 5. If or when biohazardous medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do 1 of the following:
 - a. Reject the waste and return it to the generator,
 - b. Accept the waste and transfer it directly from transporting vehicle to treatment processing unit,
 - c. Repackage the waste in accordance with R18-8-1407.

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6. The treater follows a procedure for treating or disposing of biohazardous medical waste within 24 hours of receipt of the waste or refrigerating immediately at 40°F. or less upon determining that treatment or disposal will not occur within 24 hours. Storage of refrigerated biohazardous medical waste shall not exceed 90 days;
 7. The processing area is cleared of waste and decontaminated 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.
- D. In addition to meeting the requirements of subsection (B) or (C), a person who applies for facility plan approval after the effective date of this Article shall ensure the facility is designed to meet both of the following:
1. Any floor or wall surface in the processing area of the facility which may come into contact with biohazardous medical waste shall be constructed of a smooth, easily cleanable material that is impervious to liquids.
 2. The floor surface in the treatment and storage area shall either have a curb of sufficient height to contain spills or shall slope to a drain connected to an approved sanitary sewage system, an approved septic tank system, or a collection device.
- E. The treater shall ensure the equipment meets the manufacturer's operational requirements for the duration of equipment use. Written records capable of documenting compliance with manufacturer's specifications shall be kept by the treater for the life of the equipment and made available to the Department upon request.
- F. In addition, a treater who treats by incineration shall meet both of the following:
1. The incineration method shall reduce the biohazardous medical waste, excluding metallic items, into carbonized or mineralized ash.
 2. Perform a waste determination of the ash to identify if the waste is hazardous in accordance with 40 CFR 262.11 (see R18-8-262(A)), 40 CFR 262.11, as amended as of July 1, 1995, (and no future editions), is incorporated by reference and is on file with the Department and the Office of the Secretary of State.
- G. The treater shall maintain recordkeeping of equipment maintenance and operational performance levels for 3 years. Equipment records shall include the date and result of all equipment calibration and maintenance. Operational performance level recordkeeping shall include duration of time for each treatment cycle as follows:
1. Steam treatment and microwaving treatment records including both:
 - a. The temperature and pressure maintained in the treatment unit during each cycle,
 - b. The method utilized for confirmation of temperature and pressure.
 2. Chemical disinfection treatment records describing the solution used;
 3. Incineration treatment records including the temperature maintained in the treatment unit during operation;
 4. Such other operating parameters as set forth in the manufacturer's specifications;
 5. The method used to confirm effectiveness and the test results.
- H. The treater shall make treatment records available for Departmental inspection upon request.

R18-13-1423. Approved Medical Waste Treatment Facility Plans: Substantial Changes

- A. As required by A.R.S. § 49-762.06, prior to making any change to an approved facility plan, a treater shall determine the type of change as 1 of the following:
1. A Type 1 change to an approved medical waste facility plan not described by R18-13-1423(A)(2) through (4).
 2. A Type 2 change to an approved medical waste facility in which treatment equipment is replaced with equal or like equipment, which result in either no increase to treatment capacity or in the addition of equipment which is not directly used in treatment process.
 3. A Type 3 change to an approved medical waste facility described by 1 of the following:
 - a. Treatment equipment is added, resulting in less than a 25% increase in treatment capacity;
 - b. An expansion of the facility resulting in less than a 25% increase in storage capacity;
 - c. A change in treatment technology.
 4. A Type 4 change to an approved medical waste facility described by 1 of the following:
 - a. Treatment equipment is added, resulting in a 25% increase or more in treatment capacity;
 - b. An expansion of the facility resulting in a 25% increase or more in storage capacity;
 - c. Treatment equipment is added, which 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 treater who has identified the change as described in subsection (A) shall comply with 1 of the following:
1. For a Type 1 change, make the change, without notice to, or approval by the Department;
 2. For a Type 2 change, prior to making any change, provide written notification which describes the change to the Department. No Departmental approval is required;
 3. For a Type 3 or Type 4 change, submit an amended plan to the Department for approval prior to making any change. Departmental approval is required prior to making any change.

R18-13-1424. Alternative Medical Waste Treatment Methods: Registration and Equipment Specifications

- A. A manufacturer or 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 person submitting 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 any state approvals;
 5. A description of bi-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 which demonstrates that the alternative medical waste treatment method is capable of compliance with the standards in this Article for the type of waste treated. The demonstration shall be submitted to the Department from a laboratory independent of any oversight activities by the manufacturer;

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- 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 which identify the proper type of biohazardous medical waste to be treated in the equipment and any design or equipment restrictions;
 - c. Operating procedures for the equipment which ensure the equipment complies with the treatment standards described in this Article for the type of waste treated;
 - d. Instructions for equipment maintenance, testing and calibration which ensure the equipment complies with the treatment standards described in this Article for the type of waste treated.
- B. The Department shall make a determination whether or not the registration application is administratively complete within 15 days of receipt of an application for registration. The Department shall issue an alternative medical waste treatment method registration number or denial of an application within 30 days after completion of its administrative review.

R18-13-1425. Alternative Medical Waste Treatment Methods: Generators Who Treat Waste On-site.

- A. A generator who treats biohazardous medical waste on-site utilizing an alternative treatment method shall utilize a treatment method registered in accordance with R18-13-1424, and shall follow the manufacturer's specifications for equipment

operation. An alternative treatment method is a method other than autoclaving or incineration.

- B. A generator who treats biohazardous medical waste on-site shall maintain written documentation for all of the following:
 - 1. The Departmental registration number for the alternative medical waste treatment method;
 - 2. The equipment specifications which identify the proper type of biohazardous medical waste to be treated in the equipment and any design or equipment restrictions;
 - 3. The operating procedures for the equipment which ensure the equipment complies with the treatment standards described in this Article for the type of waste treated;
 - 4. The instructions for equipment maintenance, testing and calibration which ensure the equipment complies with the treatment standards described in this Article for the type of waste treated;
 - 5. A training manual regarding proper operation of the equipment;
 - 6. A treatment record consisting of a log of the volume of medical waste treated and a schedule of calibration and maintenance performed in accordance with the manufacturer's specifications.
- D. A generator who treats who treats biohazardous medical waste on-site shall keep treatment records as described in subsection (C)(6) for 6 months. All other documentation described in this Section shall be kept for the operational life of the treatment equipment. A generator shall make documentation and records available for Departmental inspection upon request.