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Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Virginia Department of Environmental Quality
VAC Chapter Number:	9 VAC 20-120-10 et seq.
Regulation Title:	Regulated Medical Waste Management Regulations
Action Title:	Amendment 2
Date:	March 27, 2002

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The Regulated Medical Waste Management Regulations, 9 VAC 20-120-10, *et seq.* (RMWMR) establish permit requirements for the storage, treatment and disposal of regulated medical wastes (RMW). Rules for packaging, labeling and transporting RMW, as well as exemptions from regulation, are also included. Five approved treatment processes are provided for as well as provisions for establishing alternate treatment technologies.

Revisions have been made to the definition of regulated medical waste as well as to packaging, labeling and transportation requirements. Redundant sections of the regulation have been eliminated. The regulation has been updated to provide consistency with other bodies of regulation such as the Virginia Department of Labor and Industry's bloodborne pathogen

DRAFT
standard and US Department of Transportation's regulations governing the transportation of hazardous materials.

Since the proposal, in response to public comment, changes have been made to the regulation to clarify what is a regulated medical waste and what is exempt from regulation.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On April 25, 2002 the Waste Management Board approved Amendment 2 of the Regulated Medical Waste Management Regulations, 9 VAC 20-120-10 et seq.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

The Virginia Waste Management Act contained in Chapter 13, Title 10.1, Code of Virginia (1950), as amended, requires owners and operators of all facilities for the treatment, storage, and disposal of solid waste to hold a permit from the director of the Virginia Department of Environmental Quality. RMW is a type of solid waste. The Waste Management Board is authorized to promulgate and maintain regulations for the permitting process and to issue regulations necessary to supervise and control solid waste management, to abate nuisances and threats to public health, safety, or the environment (Va. Code §10.1-1402). In fulfillment of these responsibilities, the Board adopted Regulated Medical Waste Management Regulations, (9 VAC 20-120-10, *et seq.*)

The Virginia Waste Management Act can be found on http://leg1.state.va.us.

The Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not

acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

Certain waste resulting from medical services requires more prudent care and has been defined as "regulated medical waste" in the regulations. The regulations establish specific treatment and handling requirements for regulated medical waste to continue this prudent care during waste management activities. The goal or the regulation is to protect public health, safety and welfare and the environment from the harmful results of mismanagement of regulated medical waste by its generators, transporters, storers, treaters or disposers with the least possible costs and intrusiveness to the citizens and businesses of the Commonwealth.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

Modifications made to the regulations include:

?? The definition of regulated medical waste, including the definitions of "blood" and "body fluids" have been updated. The concept of the regulation of human blood and human body fluids is based on the Bloodborne Pathogen Standard 16 VAC 25-90-1910.1030 (29 CFR 1910.1030). Items that are saturated with human blood or human body fluids are considered regulated medical waste. An item is considered saturated if it is capable of releasing human blood or human body fluids in a liquid or semi-liquid state if compressed.

?? Provisions of the regulation related to "limited small clinics" have been eliminated and exemptions are based on the volume of waste generated at a facility. If facilities generate less than 100 gallons of regulated medical waste per week and store 200 gallons or less of regulated medical waste they are subject to reduced regulatory requirements. The provisions are designed to allow smaller facilities handling low volumes of waste to comply with prescriptive provisions for holding wastes rather than obtaining a permit-by-rule for on-site storage.

?? Changes to the requirements for on-site regulated medical waste storage facilities have eliminated the requirement for a permit-by-rule in lieu of complying with prescriptive provisions for holding wastes. Facilities generating 100 gallons per week or more of regulated medical waste must provide a designated storage area for all areas of the facility storing greater than 200 gallons of regulated medical waste. Specific requirements are provided for designated storage areas.

?? Modifications of regulated medical waste packaging requirements have been made so that requirements are consistent with other bodies of regulation including the Bloodborne Pathogen Standard, and the Regulations Governing the Transportation of Hazardous Materials 9 VAC 20-110-10 et seq (49 CFR 171 through 178).

DRAFT

?? Modifications to the regulation have been made to coordinate the proposed regulation with the Regulations Governing the Transportation of Hazardous Materials 9 VAC 20-110-10 et seq.

?? Modification of the permitting standards of Part X (9 VAC 20-120-680 to 9 VAC 20-120-830) has eliminated the requirements for obtaining a full permit for off-site regulated medical waste management facilities. Permit by rule will now be the only permitting mechanism for off-site facilities.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

There are no anticipated disadvantages to the public or the Commonwealth resulting from the amendment of the regulation. The definition of regulated medical waste has been clarified to the benefit of the public, the regulated community and the Commonwealth. Improved regulated medical waste identification could result in improved compliance with the requirements of the regulation. Since items that are not saturated or capable of releasing blood or body fluids in a liquid or semi liquid state are no longer considered regulated medical waste, the volume of waste requiring treatment is anticipated to decrease. Reducing the volume of wastes requiring treatment could save health care facilities treatment/disposal costs.

The reduced requirements for a "limited small clinic" in the current Regulated Medical Waste Management Regulations focus on a narrow range of facilities because of the way a "limited small clinic " is defined. The amended regulations provide reduced requirements for storage areas based on the weekly volume of waste handled by the facility as well as the total volume stored without regard to the type of facility producing the waste. The proposed requirements are more understandable and consistent with other bodies of regulation. As a result of this change of focus, Commonwealth resources can be applied to those facilities that handle larger volumes of waste and have greater potential for impacting human health and the environment.

Exemptions from permit by rule requirements have been provided for those facilities meeting certain site-specific conditions. This allows facilities to operate if they meet certain design and operation requirements without having to obtain an on-site permit by rule. The modified language of the regulation provides clear requirements for the design and operation of these "designated storage areas" and clarifies when regulated medical waste becomes subject to regulation. The proposed removal of the permit by rule requirement provides the same protective requirements for design construction and operation as a permitted operation.

DRAFT
Modifications of the regulations are proposed to make the regulations consistent with regulations of other agencies including the Regulations Governing the Transportation of Hazardous Materials and the Bloodborne Pathogen Standard. Relying on recognized standards will help to reduce confusion regarding regulatory requirements, will reduce the duplication of regulations and will eliminate unnecessary regulations. In addition, the modifications will eliminate potential conflict with federal hazardous material requirements that may "preempt" the requirements of any conflicting state provisions.

Statement of Changes Made Since the Proposed Stage

Please highlight any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication.

9 VAC 20-120-130
The definitions of "Empty" and "Contaminated" have been modified for clarity. When modifying the definition of "Empty", a statement has been added in the exemptions indicating that materials are still regulated as "regulated medical waste" if they are subject to regulation under the OSHA bloodborne pathogen standard.

A clarification of the term "caked" was provided.

9 VAC 20-120-150
A clarification was provided indicating all sharps are regulated medical waste including those used in veterinary practice.

9 VAC 20-120-370 and 9 VAC 20-120-440
The section was modified to indicate that if wastes are managed in container that is resistant to the elements a covered loading area is not required.

9 VAC 20-120-450
Requirement for signage on the doors of RMW transporters has been removed.

9 VAC 20-80-590 and 9 VAC 20-80-640
This section has been modified to allow shredding within 24 hours following treatment rather than immediately after treatment

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Comments on definitions:

DRAFT
Comments indicated that a number of the updated definitions in the regulation require further clarification. Numerous comments stated that urine should not be specifically regulated since urine is usually not considered infectious unless it contains blood. Other comments indicated that the definition of "Empty" should be limited to the first sentence of the definition and stated the additional language in the second sentence stating "in all cases liquid blood and body fluids shall be removed" is confusing. Some comments recommended that "Infection control professional" be added to the definition of "health care professional".

Agency Response:
The board has received information stating that urine is capable of transmitting disease. The regulation is designed to regulate items beyond the bloodborne pathogen standard. In most cases urine is disposed through the sanitary sewer system and this method of disposal, combined with the new exclusions for items that are "Empty" and materials that are absorbed, will minimize the actual impact of these requirements.

The definitions of "Empty" and "Contaminated" have been modified for clarity as public comments have suggested. Additional clarification has also been provided to indicate that if a material is subject to the bloodborne pathogen standard it is still a regulated medical waste.

There are several different voluntary organizations that administer certification for infection control. The board has no way to evaluate the merits of a given organization or the associated certification. These certifications are not required by Virginia law, as are certifications of doctors and nurses. Requiring independent third party state certification ensures a higher level of confidence in the individuals responsible for identifying these wastes.

Comments on containers and labeling:
Several comments were received regarding the labeling of containers of regulated medical waste. Some comments indicated that the labeling requirements would be more burdensome. Several comments indicated that waste taken to treatment facilities from outside of Virginia would not be labeled in accordance with the Virginia requirements and therefore the requirements to label the waste should be eliminated. One comment indicated that all labeling requirements should be moved to one section of the regulation.

Agency Response:
The proposed labeling requirements are less burdensome. Both the existing and proposed regulations require labels to be affixed to outer packaging. Some facilities may need to modify the way that they are currently labeling packaging and may need to obtain new or different labels. However, the regulation does not require a specific label style, so facilities may employ any labeling which fits their operations and meets the basic requirements of the regulation.

The labeling requirements do not impact facilities outside of Virginia. The only labeling requirement at treatment facilities is to provide a procedure to track the date that the material is received onsite at the treatment facility. This requirement will ensure that waste is treated within 15 days of receipt. This requirement does not have any connection with where the waste originated. The requirements exist regardless of the origin of the waste.

DRAFT
After reviewing the regulation, marking requirements were retained in separate sections. Requirements in storage sections state that the date the waste was placed in storage needs to be placed on outer packaging. This is a storage requirement, not a labeling requirement. The date is required to track 7 days until refrigeration and 15 days of storage at the site of generation.

Comments on record keeping:
Comments state that records of treatment need not be maintained by both the generating facility and the treatment facility. They recommend that records should be required at the treatment facility only.

Agency Response:
The requirement has been retained. Retaining the requirement may alert the generator when improper activities are occurring during transportation or treatment of regulated medical waste.

Comments related to the definition of regulated medical waste:
Comments suggest that the regulation of sharps should continue to include sharps produced from veterinary practice. Several comments indicated that the definitions included in the regulation should be more consistent with either OSHA regulations or Hazardous Material Regulations.

Agency Response:
Sharps generated from veterinary practice are not intended for exclusion from regulation. The proposed definition of sharps and regulated medical waste does not exclude sharps from veterinary practice. However, to eliminate confusion a reference to "veterinary practice" has been added to the section.

The RMWMR regulates different materials from OSHA and the DOT Hazardous Materials Regulations. OSHA only regulates materials that could contain bloodborne pathogens. RMWMR regulate other materials that can cause disease. The Hazardous Material Transportation Regulations includes animal parts and animal blood in definitions of infectious materials. RMWMR do not regulate animal waste unless the animal has been intentionally infected with human disease. All definitions have been written recognizing the other applicable regulations, but all definitions will not be identical due to the different materials being regulated under the RMWMR.

Comments regarding handling practices:
Comments indicate that RMW need not be refrigerated unless it has a potential to putrefy. One comment stated that the change in holding waste on loading docks from 7 days to 24 hours is unreasonable. One comment indicated that the statement regarding 24 hours layover during transport should be increased to 62 hours to allow for weekends.

Agency response:
Since virtually all regulated medical waste except possibly sharps deal with blood, body fluids and anatomical wastes, all of the wastes have a potential to putrefy or provide a potential for bacteria to multiply. Refrigeration will reduce this potential.

DRAFT
Although holding times have changed on the loading dock, new exemptions from permitting are described in this section of the regulations. These new exempt waste holding options offer equal/additional flexibility when managing waste prior to transport.

Waste should be expeditiously treated. Allowing 62 hours for waste to be stored during layover does not move the waste forward toward treatment.

Comments on shredding:
One comment indicated the difficulties associated with shredding or grinding regulated medical waste. The comment indicated that the size of 3/4 inch was difficult to achieve. It also indicated that shredding immediately following treatment was impractical due to the nature of plastic materials following treatment.

Agency response:
Rendering materials unrecognizable as medical in origin is the goal of the 3/4 inch shredding requirement. Since variances are already available and have been granted to this requirement where appropriate, the requirement has been retained. The requirement to shred immediately after treatment has been modified to within 24 hours of treatment due to difficulties with some wastes when they are still hot.

Other comments:
One comment indicated that the requirement for signage on the door of trucks hauling RMW could conflict with DOT requirements

One comment indicated that the certified operators course for steam sterilization is difficult because much of the material in the exam deals with incinerator operators.

One comment suggested inserting the term "knowingly" as in no person shall knowingly receive for transportation (several sections).

Deleting reference to mycobacteria, which has been eliminated in other sections.

Agency response:
The requirement for signage has been removed.

Neither the operators course nor the certification program is administered by DEQ. Any suggestions for modification of the program should be sent to the Board for Waste Management Facility Operators.

The Code of Virginia provides for criminal penalties for willful violation of the regulations. The medical waste regulations currently assign some responsibility for ensuring that reasonable steps are taken to ensure that regulated medical waste does not make its way into the solid waste stream during transport or during disposal in a landfill. Inserting the word "knowingly" would allow waste handlers to simply state that they did not know that medical waste was present thereby avoiding responsibility for the materials that they manage.

DRAFT

The section of the regulations that provides for cleaners effective against mycobacteria deals with transportation of regulated medical wastes. The cleaner is intended to be used in the event of a spill (truck wreck, accident, dropping a bag during loading activities). The mycobateria reference was removed from other sections of the regulations, such as cart cleaning, because liberal amounts of water and other cleaners are available for and are equally effective in those cleaning situations. In addition, cleaners effective against mycobacteria often create problems for sewage plant operators. A more effective cleaner is warranted in the absence of liberal water supplies.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

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9 VAC 20-120-10

This section has been modified to eliminate unnecessary definitions and add additional definitions where clarification is necessary. Major changes to this section include the addition of definitions for "blood" and "generate" as well as modifications to the definitions of "body fluids" and "storage". Since the proposal, clarifications have been made to the definitions of "Contaminated" and "Empty".

9 VAC 20-120-40

This section has been simplified to state that all procedures under the law may be used in enforcement rather that citing specific procedures under the law.

9 VAC 20-120-50

This section has been updated to eliminate passed deadlines, to require submission of certain new information required by the proposed regulations, and to replace existing permits issued under these regulations with a permit-by-rule.

9 VAC 20-120-60

This section has been modified to state that this modification of the Regulated Medical Waste Management Regulations replaces all previous versions of the regulations including the regulations effective June 29, 1994.

9 VAC 20-120-70

This section has been modified to include all applicable regulatory references related to these regulations.

9 VAC 20-120-120

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This section has been modified to eliminate obsolete requirements. This section originally specified regulations for smaller facilities or "limited small clinics". The proposed provisions of 9 VAC 20-120-170 include provisions for regulation based on the volume of waste produced rather than the size of the facility itself.

9 VAC 20-120- 130

This section has been modified to exempt items from consideration as regulated medical waste. Lists of exempt items have been provided including items that have been used for personal hygiene, certain empty items used to collect fluids from or administer fluids to patients, particular items that may have contacted a patient's mucous membranes and certain absorbent materials containing with blood and body fluids. Since the proposal, clarifications have been made indicating that if a material is subject to regulation under the bloodborne pathogen standard it is considered regulated medical waste and is not exempt from regulation.

9 VAC 20-120-150

The list of regulated medical wastes has been modified to recognize the new definitions of blood and body fluids. The definition of sharps has also been modified to include needles, syringes with attached needles, suture needles, and scalpels regardless of whether they have been used in patient care. Since the proposal, the regulations have been clarified with regard to sharps generated by veterinary practice.

9 VAC 20-120-170

This section has been modified to provide for the proper storage of regulated medical wastes on loading docks, at facilities generating 100 gallons/week or more, and at facilities generating less than 100 gallons/week of RMW.

9 VAC 20-120-210

This section has been modified to be consistent with the packaging requirements of the Department of Labor and Industry (OSHA Bloodborne Pathogen Standard), and federal requirements for the packaging of hazardous materials.

9 VAC 20-120-220

Labeling requirements have been updated to consider the federal requirements for packaging hazardous materials and new procedures for labeling during storage.

9 VAC 20-120-230

Requirements on the transportation of etiologic agents have been updated be consistent with federal requirements for the transportation of hazardous materials.

9 VAC 20-120-240

Requirements regarding the packaging of sharps have been modified to incorporate the requirements for the packaging of sharps from the Bloodborne Pathogen Standard administered by the Department of Labor and Industry.

9 VAC 20-120-250

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This section has been modified to remove specific requirements for protective equipment.

9 VAC 20-120-260
Labeling requirements have been updated. Cart cleaning has been modified to remove the requirement for a disinfectant effective against mycobacteria. The technical advisory committee indicated thorough cleaning would be as effective for the removal of any contaminants from reusable containers and cleaning solutions would be straightforward to dispose. The section stating that unloading should be accomplished by mechanical means has also been eliminated.

9 VAC 20-120-280
This section was modified to provide a more generalized approach to cleanup. The original language was viewed as being too prescriptive and did not allow appropriate flexibility.

9 VAC 20-120-300
This section was modified to clarify that properly constructed grinding or compaction devices may be used to reduce the volume of waste at the point of generation.

9 VAC 20-120-330
This section was modified to clarify the applicability of storage requirements to various types of facilities and circumstances.

9 VAC 20-120-340
This section was modified to clarify that seams in a tile floor are allowed in a storage area, as long as the floor has been appropriately sealed.

9 VAC 20-120-360
The beginning of the seven-day timeframe until refrigeration is required was clarified in this section. Placement of regulated medical waste in a designated storage area begins the seven-day timeframe. In addition, rather than requiring 30 days until waste is treated, 15 days of storage is allowed at a generating facility and 15 days of storage prior to treatment is allowed at a treatment facility. These requirements will be more enforceable and place responsibility for tracking independent storage timeframes with the facility in control of the waste.

9 VAC 20-120-370
Since the proposal, the section was modified to indicate that if wastes were managed in a container that is resistant to the elements a covered loading area is not required.

9 VAC 20-120-380
This section references 9 VAC 20-120-260 rather than reiterating the requirements for reusable carts here.

9 VAC 20-120-390
This section has been modified to remove specific requirements for protective equipment.

9 VAC 20-120-410

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This section was modified to clarify that cracked or damaged floor coverings may not be used in transport vehicles. In addition, cleaning requirements have been clarified. Rather than requiring cleaning after every 24-hour period of use, cleaning is required when wastes are spilled.

9 VAC 20-120-430

The beginning of the seven-day timeframe until refrigeration is required was clarified in this section. Placement of regulated medical waste in a designated storage area begins the seven-day timeframe. Allowing 24 hours for storage during transport has been placed in this section, having been removed from the definition of "storage".

9 VAC 20-120-440

Since the proposal, the section was modified to indicate that if wastes were managed in a container that is resistant to the elements a covered loading area is not required.

9 VAC 20-120-450

Since the proposal, the requirement for signage on the doors of waste transporters has been removed.

9 VAC 20-120-460

This section references 9 VAC 20-120-270 rather than reiterating the requirements for spill containment and cleanup kits here. In addition, this section references 9 VAC 20-120-280 rather than reiterating the requirements for spill cleanup here.

9 VAC 20-120-480

The requirement for transporter registration has been modified from 30 days prior to transport to prior to transport. In addition, the requirements for a change of legal name, corporate ownership or the chief executive officer of a transporter have been clarified.

9 VAC 20-120-500

This section references 9 VAC 20-120-260 rather than reiterating the requirements for reusable carts here.

9 VAC 20-120-530

This section has been modified to eliminate the requirement to exclude the heat value of the waste in maintaining the secondary chamber temperature. This requirement was modified to be consistent with the air regulations for medical waste incinerators.

9 VAC 20-120-560

This section has been modified to remove specific requirements for protective equipment.

9 VAC 20-80-590

This section has been modified to allow shredding within 24 hours following treatment rather than immediately after treatment.

9 BAC 20-80-640

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This section has been modified to allow shredding within 24 hours following treatment rather than immediately after treatment.

9 VAC 20-120-680
This section has been modified to eliminate references to permitting procedures consistent with a full permit and add procedures for permit by rule. Procedures for full permits have been eliminated throughout Part X.

9 VAC 20-120-690 through 9 VAC 20-120-720
This section has been modified to eliminate references to permitting procedures and terminology consistent with a full permit and add procedures for permit by rule. Procedures for full permits have been eliminated throughout Part X.

9 VAC 20-120-730
This section has been modified to eliminate references to permitting procedures consistent with a full permit and add procedures for permit by rule. In addition, rather than requiring 30 days until waste is treated, 15 days of storage is allowed at a generating facility and 15 days of storage prior to treatment is allowed at a treatment facility. This particular section of the regulations provides the requirements allowing tracking of the waste once it has been received at an off-site treatment facility. These requirements will be more enforceable and place responsibility for tracking independent storage timeframes with the appropriate facility.

9 VAC 20-120-740 through 9 VAC 20-120-810
This section has been modified to eliminate references to permitting procedures and terminology consistent with a full permit and add procedures for permit by rule. Procedures for full permits have been eliminated throughout Part X.

Appendix 10.1
This section has been eliminated since it references amendment procedures consistent with full permits. Procedures for full permits have been eliminated throughout Part X.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The regulations protect the public's health, safety and welfare and the environment from harmful results of the mismanagement of regulated medical wastes. However, Amendment 2 of the Regulated Medical Waste Management Regulations has no other direct impact on the institution of the family.