Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	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:	11/17/00

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary*

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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 is further authorized 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

Purpose*

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed 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.

Comments received during the three-year review and the NOIRA comment periods indicated that some of the requirements should be clearer and less vague. In particular, commenters suggested revisions to the definition of regulated medical waste as well as to packaging, labeling and transportation requirements. Further clarity can be achieved by elimination of several redundant sections. The regulations 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. The proposal also provides consistency with other bodies of regulation such as the Virginia Department of Labor and Industry bloodborne pathogen standard

and US Department of Transportation regulations governing the transportation of hazardous materials.

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 providing detail of the regulatory action's changes.

During the three-year periodic review, the department determined that several areas of the regulation needed amendment, including:

1. Definition of the concepts of generation, storage and accumulation;
2. Exemption of items used for personal hygiene;
3. Requirements for the temporary storage of RMW;
4. Requirements related to the transportation of hazardous materials; and
5. Consolidation of the text of regulation and elimination of redundant requirements.

Comments received in response to the NOIRA or the advice of the technical advisory committee (TAC) lead to substantive modifications to the regulation including:

- The definition of regulated medical waste, including the definitions of "blood" and "body fluids", was updated. The department based the concept of the regulation of human blood and human body fluids on the Bloodborne Pathogen Standard administered by the Virginia Department of Labor and Industry. 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 in lieu of regulation based on the volume of waste generated at a facility. Facilities generating less than 100 gallons per week of regulated medical waste and storing 200 gallons or less of regulated medical waste are subject to reduced regulatory requirements. The provisions are designed to allow smaller facilities handling low volumes of waste to comply with specific requirements rather than obtain 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 specific on-site storage requirements. 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. Designated storage areas must meet specific requirements in the proposed regulation.
- 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, administered by the Department of Labor and Industry and the Regulations Governing the Transportation of Hazardous Materials 9 VAC 20-110-10 et seq., administered by the Virginia State Police.

- Modifications to the regulation were 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 have been made eliminating the requirements for obtaining a full permit for off-site regulated medical waste management facilities. Permit by rule has always been an option and will now be the only permitting mechanism for off-site facilities.

Issues*

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary 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 proposed 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 proposed 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 proposed 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.

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 requirements that may "preempt" the requirements of any conflicting state provisions.

Locality Particularly Affected*

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality bears a disproportionate material impact due to this regulatory revision.

Public Participation*

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal.

In addition to any other comments, the Waste Management Board is seeking comments on the costs and benefits of the proposal. Anyone wishing to submit written comments for the public comment file may do at the public hearing, by mail, by fax at 804-698-4327, or e-mail to mjdieter@deq.state.va.us. Written comments shall include the name and address of the commenter. In order to guarantee that comments will considered, the comments must be received by the close of the comment period. Oral comments may be submitted at the public hearing.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; e) the projected cost of the regulation for affected individuals, businesses, or other entities; and f) an estimate of the impact of the proposed regulation upon small businesses as defined in § 9-199 of the Code of Virginia or organizations in Virginia.

There are currently over 20 permitted on-site storage areas that must be inspected on a routine basis. The regulations have been modified so on-site storage facilities are required to meet a standard, but may not be required to hold a permit. Inspections will now occur when an incident is reported, or when the department wishes to concentrate resources on storage facility inspections.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

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".

9 VAC 20-120-40
This section has been simplified to state that all procedures under the law may be used in enforcement rather than 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 regulation, and to replace existing permits issued under this regulation 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 regulation 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 this regulation.

9 VAC 20-120-120
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: 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 contaminated with blood and body fluids.

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.

9 VAC 20-120-170
This section has been modified to recognize the proper storage of regulated medical wastes on loading docks, in facilities generating 100 gallons/week or more, and in 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 to 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
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 20-120-380

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

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 20-120-450

This section has been modified to have a specific letter size requirement, which is more enforceable than "large" lettering previously required.

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 20-120-680
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 regulation 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.

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The department has coordinated with other regulations, rather than retaining the requirements of the existing Regulated Medical Waste Management Regulations or creating new requirements. Both the OSHA requirements for the Bloodborne Pathogen Standard administered by the Virginia Department of Labor and Industry and the requirements of the Regulations Governing the Transportation of Hazardous Materials were used as the basis for the packaging and

transportation requirements for regulated medical waste. By incorporating the provisions of these regulations, the department has avoided duplicative or conflicting regulation of the same activity.

The definition of regulated medical waste was examined and updated. Existing definitions from a number of sources were evaluated during the development of the proposal. Recent Virginia legislation, the regulations of other states and the definitions used in federal programs were considered. The definition of "body fluids" has been modified to include specific body fluids and not "any liquid emanating or derived from humans and animals," as is the case in the existing regulation. The proposed regulation provides for a specific list of body fluids that are of particular concern. In addition, the proposed regulation also provides a list of specific items that may contact body fluids, but will not be considered medical waste because only residue of these body fluids typically remains on the item when disposed. Provisions that exempt items that are not saturated and are stained with blood or body fluids were added. These provisions are consistent with the Bloodborne Pathogen Standard under OSHA and are similar to provisions used in numerous other states.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

During the public comment period for the Regulated Medical Waste Management Regulations, 9 VAC 20-120-10 et seq., 19 different individuals representing 13 different groups provided public comment. Sixteen commenters were associated with health care facilities, 2 commenters represented facilities treating/transporting regulated medical waste, and one commenter represented a manufacturer of medical waste handling equipment. The following are the comments offered by the commenters:

C: Several commenters indicated that the regulation should be based on sound science.

R: The department has based the regulation on the premise that some wastes require more prudent care. We believe wastes are handled on a scientific basis. These wastes have been identified as regulated medical wastes.

C: Some commenters provided recommended definitions of regulated medical waste and/or the materials that make up regulated medical waste such as blood, body fluids, pathological waste and laboratory wastes. Many recommended definitions were based on HB930 (proposed and carried over during the 2000 legislative session), OSHA, or the definitions of other states. Other commenters stated that the definitions contained in certain bodies of regulation or law should be the basis for a modification to the Virginia regulations. One commenter indicated that the materials that are subject to regulation should not change, but the definition of regulated medical waste should be reviewed for clarity. Several commenters suggested regulated medical waste should be regulated differently because landfill workers and the general community are not at risk from hospital waste and because no incidents or problems in a community have resulted from the disposal of hospital waste.

R: Many definitions and concepts were evaluated during the development of the proposed regulations. Model regulations, the regulations of other states and numerous other references were considered during the development process. Clarifications of the regulations have been made where necessary. The concept of regulation is based on, but is not identical to, the OSHA Bloodborne Pathogen Standard.

The department believes that landfill and other waste management workers may be at risk from splashes and punctures from regulated medical waste. There have been several incidents in the state of worker exposure to sharps and other regulated waste. OSHA regulation considered waste workers in the development of the Bloodborne Pathogen Standard, and the department has considered the waste worker in the development of this regulation.

C: Several commenters stated that diapers, and sanitary napkins should always be exempt from regulation. In addition, several stated that a "small amount" needed to be defined. These concerns all are related to the same section of the regulations which provide exemption from the definition of regulated medical waste.

R: This section of the regulation covering these two issues has been modified to eliminate diapers and sanitary napkins from regulation. In addition, the term "small amount" has been eliminated from the regulation. The set of items exempt from being considered regulated medical waste has been expanded to include items which may have contacted a patients mucous membranes but cannot splash or stick health care or waste workers.

C: Commenters from the treatment/transportation facilities indicated that the regulation was inconsistent with federal DOT requirements and provided detailed comments to correct these requirements. Comments regarding inconsistencies addressed transportation in general as well as packaging and labeling requirements. Several commenters made general comments that the regulation should be consistent with other bodies of regulation.

R: The proposed regulations are updated with reference to transportation, transport, packaging, and labeling to be consistent with federal DOT requirements and other bodies of regulation.

C: Commenters stated that the requirements for personal protective equipment were too specific and did not allow flexibility to appropriately address many situations.

R: Requirements for personal protective equipment have been broadened to provide appropriate flexibility.

C: Several commenters stated that the spill containment and cleanup procedures required modification. Some stated that cleaning options were too limited and other methods could be used with equal effectiveness.

R: A broader approach has been provided for spill containment and cleanup. In addition, cleaning requirements allow for flexibility in areas where routine cleaning is performed.

C: Several commenters recommended clarification of the point in time when refrigeration of regulated medical waste must begin. One commenter stated that because waste is moved so quickly, requirements for refrigeration should be eliminated.

R: Time allowed for on-site storage and off-site storage of regulated medical wastes have been modified. In addition, the beginning of the time refrigeration begins has been clarified, where the time in storage is known. Refrigeration is always required if total time in storage is unknown.

C: Several commenters recommended eliminating the requirements preventing use of floors with seams in regulated medical waste storage areas because hospital disinfectants can adequately clean these seams.

R: The regulation has been modified to allow storage in areas with seamed floors as long as the floor has been appropriately sealed with wax.

C: One commenter indicated that individuals developing the regulation should be on the "same page", meaning that they should strive for a common goal.

R: Members of the TAC came from a variety of backgrounds but had the common goal of developing an understandable enforceable regulation.

C: One commenter recommended that a certain group be involved in the development of the regulation.

R: The recommended group was represented on the TAC.

C: One commenter suggested that air emissions should defer to federal air standards.

R: The regulations are consistent with applicable air standards.

C: One commenter suggested that the requirements for shredding of treated waste should be reconsidered.

R: Requirements regarding shredding have not been revised. Shredding requirements give the facility receiving treated waste the option (with a variance) for changing the way treated waste appears at their facility (shredded or unshredded). Handling practices can be specific to, and at the discretion of, the receiving facility.

C: One commenter provided certain publications to be used as the basis for the evaluation of alternate treatment technologies.

R: Published standards were considered when developing the proposed regulation. Many standards/recommendations provided are not final and are still under development. When treatment standards are finalized, they can be considered in the development for inclusion in the regulations.

C: One commenter stated that fiscal responsibility should play a role in the development of the regulations.

R: The regulations have been written such that items that are not capable of releasing blood or body fluids are not considered regulated medical waste. This may reduce the quantities of waste requiring treatment and may help to reduce the cost of disposal.

C: One commenter said that red bags are only necessary as the outer layer, not in all the layers of a multiple layers package.

R: The regulations have been written allowing for the use of one red bag in the packaging of regulated medical waste.

C: One commentor stated that specific approvals should not be necessary to transport less than 64 gallons.

R: Federal transportation regulations apply no matter what the volume of medical waste transported. The department will require registration of all of these transporters.

C: One commenter stated that materials in a cart should be considered transferred "under cover" as required by the regulations.

R: We believe the existing regulation allows for waste transfer when it says that if an activity is transient in nature such as collection of waste packages from a professional office, then a cover, floor or pavement is unnecessary.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The agency, through a thorough examination of the regulation and relative public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The agency intends to review the regulation every three years based on the following goals:

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.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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.