Form: TH- 06

Virginia Regulatory Town Hall

Periodic Review and Notice of Intended Regulatory Action 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:	Periodic Review
Date:	February 10, 2000

This information is required pursuant to the Administrative Process Act § 9-6.14:25 and Executive Order Twenty-Five (98) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision, instead give a general description of the regulation and alert the reader to its subject matter and intent.

The Regulated Medical Waste Management Regulations, 9 VAC 20-120-10, *et seq.* (RMWMR) establishes 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 for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

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, or disposal of solid waste to hold a permit from 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.*)

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

Members of the medical community and waste industry provided comments including but not limited to the following:

1. Management of regulated medical waste should be based on sound scientific evidence.

2. Current regulations may not be effective because they are viewed by some as subject to interpretation and as resulting in unjustified expense in some instances.

3. The regulations need to be more clearly written and more specific.

Additional public comments summarized are in Attachment 1

A technical advisory group will be formed to develop a proposal.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The specific and measurable goals of the regulation are 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. The department has determined that the regulations are necessary to accomplish these goals.

Based on the above goals, the regulations appear to be performing as intended. Due to a growing awareness of the medical waste regulations within the regulated community, there is a perception that interpretations of the regulations by the DEQ have changed over time. The regulated community commented during the public comment period for this periodic review that they perceived the department as having been inconsistent and overly stringent in its interpretations of the regulations. In addition, from the public comments received, it appears that the regulation could be more understandably written, at least in some areas.

Several public comments indicated that a particular hospital was spending significantly more to dispose of regulated medical waste compared to last year. Since the regulations have not been changed since June of 1994, it may be that the burden and cost of the regulation is not just due to the regulation itself but as some have suggested in their comments it is due to recent enforcement efforts. Hospitals have chosen to err on the side of being conservative with their medical waste stream and have incurred an increased cost of disposal.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

The department has considered developing guidance to clarify some provisions of the regulations. The comments received during the public comment period indicate that the regulated community perceives that the regulations are more burdensome than necessary and the regulations are difficult to understand. Guidance would insure consistent interpretations from the department and clarification to the regulated community.

The department has considered modifying the regulations in order to eliminate potentially redundant sections, clarify permitting requirements, add new definitions, examine conformity of the state regulations to federal transportation requirements, and clarify several existing definitions.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The agency recommends the amendment of the regulation. This recommendation is based on the following:

1. Clarification may be needed in some of the areas of the regulations where public comments have indicated the regulated community needs direction.
2. The regulation is repetitive in some areas. Eliminating repeated information and consolidating this information will serve to further clarify the regulation.

Substance

Please detail any changes that would be implemented.

An amendment of the regulations may include but will not be limited to the following:

1. The concepts of generation, storage, and accumulation.
2. The issue of storage of separately accumulated objects for personal hygiene, such as sanitary napkins and diapers.
3. The issue of temporary storage of RMW.
4. The transportation of hazardous materials as required in federal regulation.
5. Consolidation of the regulations and elimination of redundant requirements.

In addition, the Board may consider additional comments received in response to the NOIRA or activities of the technical advisory committee (TAC) which will assist the department with the development of the proposal.

KEY TO COMMENTERS

Title	First	Middle	Last	Job Title	Company Name	Code (4 letters ma
Mr.	Reed	B.	Kennedy	Chief Operating Officer	Montgomery Regional Hospital	MRH
Dr.	Jack	C.	Turner	Director of Laboratories	Danville Regional Medical Center	DRM
Mr.	Donald	S.	Buckley	President	Chesapeake General Hospital	CGH
Mr.	Martin		Casey	Director Radiology and Facilities Management	Chesapeake General Hospital	CAS
Mr.	Harry	H.	Munari	Vice President	Chesapeake General Hospital	MUN
Dr.	Billy	B.	Richmond	Department of Medicine/Infectious Diseases	Chesapeake General Hospital	RIC
Dr.	Arthur	S.	Giroux	Chief, Department of Pathology	Chesapeake General Hospital	GIR
Dr.	Adam		Billet	Vice Chief, Department of Surgery	Chesapeake General Hospital	BIL
Dr.	Ahmed		Rahman	President-Elect, Medical Staff	Chesapeake General Hospital	RAH
Dr.	Matthew		Tignor	Department of Medicine/Infectious Diseases	Chesapeake General Hospital	TIG
Dr.	Steven	B.	Powers	Chief, Department of OB/Gyn	Chesapeake General Hospital	POW
Dr.	Nasrollah		Fatehi	Chief, Department of Surgery	Chesapeake General Hospital	FAT
Dr.	Anthony	J.	Distasio, II	Department of Surgery	Chesapeake General Hospital	DIS
Dr.	Jeffrey		Powell	Chairman, OR Committee	Chesapeake General Hospital	JPO
Ms.	Julia	S.	Riddle	Vice President of Nursing	Chesapeake General Hospital	RID
Ms.	Barbara		Mullins	Chairperson Safety/Infection Control Committee	Norton Community Hospital	NCH
				Southwest Virginia Regional Infection Control Council		SVR
Ms.	Constance	D.	Jones	RN, CIC		JON
Mr.	Elwood	B.	Boone, III	Associate Administrator	Chippenham Medical Center	CMC

Mr.	Ronald	A.	Bouchard	Chief Administrative Officer	University of Virginia Health System	UVA
Mr.	Paul	A.	Slagenweit	Vice President, Human Resources	Southampton Memorial Hospital	SMH
Ms.	June	M.	Duck	Coordinator, Health Services	Southampton Memorial Hospital	DUC
Ms.	Glenda		Gotshall	Infection Control Coordinator	Mary Washington Hospital	MWH
Mr.	Bill		James	Director, Environmental Services	Mary Washington Hospital	JAM
Ms.	Carolyn		Palmer	BSN, CIC	Augusta Medical Center	AMC
Dr.	Robert	W.	Cantrell	Vice President and Provost for the Health System	University of Virginia	CAN
Mr.	Ralph	H.	Wheeler	Director of Engineering, Security and Safety	Bon Secours-Richmond Health Corporation	BSR
Dr.	Virginia	D.	Wells	Chair, Infection Control Committee	Williamsburg Community Hospital	WCH
Dr.	Nancy		VanBuren	Chairperson, Infection Control Committee	Wellmont Lonesome Pine Hospital	WLP
Ms.	Judy		Dickenson	Infection Control Practitioner	Wellmont Lonesome Pine Hospital	DIC
Ms.	Frances	S.	Bonardi	Vice President, Hospital Operations	Martha Jefferson Hospital	MJH
Mr.	Michael	R.	Spatz	Director, Support Services	Martha Jefferson Hospital	SPA
Dr.	Allan	J.	Morrison, Jr.	Epidemiologist, Inova Health System	Infectious Diseases Physicians, Inc.	IDP
Mr.	Timothy	E.	Wildt	Chief Executive Officer	Virginia Hospital & Healthcare Association	VHH
Ms.	Elizabeth		Brown	RN, MSA, CCM	Maryview Medical Center	MMC
Mr.	Thomas	P.	Herbert, P.E.	Engineering Manager	American Waste Industries, Inc.	AWI
Mr.	Samuel	F.	Lillard, FACHE	Executive Vice President/Administrator	Bon Secours Richmond Community Hospital	RCH
Ms.	Nancy		Davis, RN, CIC		Western State Hospital	API
Ms.	Linda		Adcock, RN, BSN, CIC		Chesapeake General Hospital	ADC

COMMENTS - ATTACHMENT 2

Code	Comment	Number	Citation
MRH	standards promulgated by DEQ and EPA are not consistent, at least in the interpretation of standards.	1	NA
MRH	the regulation are not clear for hospitals as to what is medical waste and what is not	2	NA
MRH	enforcement has led hospitals to be overly conservative with categorization of medical waste	3	NA
DRM	regulation of medical waste should be based on solid scientific evidence	1	NA
DRM	sharps clearly should be sterilized and packaged, many other materials should not be regulated	2	NA
DRM	new regulations should be evaluated for potential benefits and costs	3	NA
CGH	management of medical waste should be based on sound scientific evidence	1	NA
CGH	infection from wastes other than sharps is non-existent	2	NA
CGH	what constitutes regulated medical waste should be clearer and not left open to interpretation	3	150
CGH	clarify requirements for disposal of diapers and sanitary napkins	4	130D1
CGH	define what is a small amount of body fluid or blood	5	130D2
CGH	disposal of regulated medical waste has become more costly than it needs to be	6	NA
CGH	current regulations are not effective because they are vague, subject to interpretation, and result in unjustified expense	7	NA
CGH	it is necessary to regulate some medical waste but this must be based on the most current scientific evidence	8	NA
CGH	other states regulations should be used to develop regulations that are less burdensome	9	NA
CGH	the regulations need to be more clearly written, and more specific	10	NA
NCH	management of medical waste should be based on sound scientific evidence	1	NA
NCH	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	2	NA
NCH	health care providers are being singled out for regulation when the same wastes can be generated in a household	3	NA
NCH	the regulations are not clearly written or easily understood	4	NA
JON	management of medical waste should be based on sound scientific evidence	1	NA
JON	infection from wastes other than sharps is non-existent	2	NA
JON	surveillance for medical wastes at landfills has a potential for bringing workers into contact with those waste and home generated wastes	3	NA
JON	regulations are inconsistently applied	4	NA

JON	regulations are responsible for costly disposal of waste	5	NA
JON	current regulations are not effective because they are vague, subject to interpretation, and result in unjustified expense	6	NA
JON	management of medical waste should be based on sound scientific evidence	7	NA
JON	other states regulations should be used to develop regulations that are less burdensome	8	NA
JON	the regulations need to be more clearly written, and more specific	9	NA
CMC	current regulations are vague, subject to interpretation, and result in confusion and inconsistent enforcement	1	NA
CMC	because of implementation of OSHA Bloodborne Pathogen standards, and precautions taken at the landfill, the risk of disease transmission is almost non-existent	2	NA
CMC	provide a clear definition of regulated medical waste	3	150
CMC	regulations are inconsistently applied. acute care facilities are being singled out and households are not regulated	4	130C2
CMC	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	5	NA
UVA	regulations are not clearly written and are subject to interpretation	1	NA
UVA	there is a relatively low risk outside the health care setting for transmission of disease from medical waste	2	NA
UVA	regulations are necessary but are expensive to implement because of recent interpretations	3	NA
UVA	regulations should focus on the potential hazard from sharps or splash rather than absorbed blood or body fluids	4	150
SMH	infection from wastes other than sharps is non-existent	1	NA
SMH	regulations are too vague and broad and enforcement has become rigid and inconsistent	2	NA
SMH	dispersing diapers from child and long-term care is inconvenient and unnecessary	3	130D1
SMH	define what is a small amount of body fluid or blood	4	130D2
SMH	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	5	NA
SMH	current regulations are not effective because they are vague, subject to interpretation, and result in unjustified expense	6	NA
SMH	management of medical waste should be based on sound scientific evidence	7	NA
SMH	other states regulations should be used to develop regulations	8	NA
SMH	the regulation need to be more clearly written, and more specific	9	NA
DUC	infection from wastes other than sharps is non-existent	1	NA
DUC	regulations are too vague and broad and enforcement has become rigid and inconsistent	2	NA
DUC	dispersing diapers from child and long term care is inconvenient and unnecessary	3	130D1

DUC	define what is a small amount of body fluid or blood	4	130D2
DUC	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	5	NA
DUC	current regulations are not effective because they are vague, subject to interpretation, and result in unjustified expense	6	NA
DUC	management of medical waste should be based on sound scientific evidence	7	NA
DUC	other states regulations should be used to develop regulations	8	NA
DUC	the regulations need to be more clearly written, and more specific	9	NA
AMC	urine and IV spikes should not be considered medical waste	1	150
CAN	regulations are not clearly written and are subject to interpretation	1	NA
CAN	there is a relatively low risk outside the health care setting for transmission of disease from medical waste	2	NA
CAN	regulations are necessary but are expensive to implement because of recent interpretations	3	NA
CAN	regulations should focus on the potential hazard from sharps or splash rather than absorbed blood or body fluids	4	150
BSC	current rigid interpretation of DEQ regulation is inconsistent with OSHA Bloodborne Pathogen Standard	1	150
BSC	regulation are responsible for costly disposal of waste	2	NA
BSC	surveillance for medical wastes at landfills has a potential for bringing workers into contact with those waste and home generated wastes	3	NA
BSC	regulations are inconsistently applied	4	NA
BSC	management of medical waste should be based on sound scientific evidence	5	NA
BSC	adopt ATSDR definition of medical waste or one with similar scientific basis	6	150
BSC	provide/require continuing education programs for occupational groups that handle medical waste	7	NA
BSC	evaluate alternative treatment technologies	8	640
WCH	definition of regulated medical waste should be consistent with CDC guideline for hospital wastes where prudent handling would be appropriate	1	150
WCH	regulations are responsible for costly disposal of waste	2	NA
WLP	management of medical waste should be based on sound scientific evidence	1	NA
WLP	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	2	NA
MJH	surveillance for medical wastes at landfills has a potential for bringing workers into contact with those waste and home generated wastes	1	NA
MJH	current rigid interpretation of DEQ regulation is inconsistent with OSHA Bloodborne Pathogen Standard	2	150
MJH	regulations are inconsistently applied	3	NA

MJH	management of medical waste should be based on sound scientific evidence	4	NA
MJH	adopt ATSDR definition of medical waste or one with similar scientific basis	5	150
MJH	provide/require continuing education programs for occupational groups that handle medical waste	6	NA
MJH	evaluate alternative treatment technologies	7	640
SPA	regulations are responsible for costly disposal of waste	1	NA
SPA	regulations should only apply to wastes once they leave the hospital	2	NA
SPA	regulations are inconsistently applied	3	NA
SPA	the same item may be regulated differently if it is not generated in the hospital setting	4	130
IDP	risks to the public at large from medical waste are negligible	1	NA
IDP	surveillance for medical wastes at landfills has a potential for bringing workers into contact with those waste and home generated wastes	2	NA
IDP	infection from wastes other than sharps is non-existent	3	NA
IDP	urine should not be considered medical waste	4	150
IDP	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	5	NA
VHH	other states regulations should be used to develop regulations that are less burdensome	1	NA
VHH	home health care also produces these wastes but they are unregulated with no effect noted	2	130C2
VHH	regulations are causing more wastes to be incinerated which causes greater degradation of the environment	3	NA
VHH	regulations need to be more clearly written an made more understandable	4	NA
MMC	support clear regulations	1	NA
RCH	management of medical waste should be based on sound scientific evidence	1	NA
RCH	infection from wastes other than sharps is non-existent	2	NA
RCH	what constitutes regulated medical waste should be clearer and not left open to interpretation	3	150
RCH	define what is a small amount of body fluid or blood	4	130D2
RCH	disposal of regulated medical waste has become more costly than it needs to be	5	NA
RCH	regulations are not effective because they are vague, are subject to interpretation, and result in unjustified expense	6	NA
RCH	it is necessary to regulate some medical waste but this must be based on the most current scientific evidence	7	NA
RCH	other states regulations should be used to develop regulations that are less burdensome	8	NA
RCH	the regulations need to be more clearly written, and more specific	9	NA

SVR	management of medical waste should be based on sound scientific evidence	1	NA
SVR	regulations are responsible for costly disposal of waste	2	NA
SVR	same wastes can be generated in a household	3	130C2
SVR	the regulations need to be more clearly written, and more specific	4	NA
MWH	current regulations are vague, confusing, and subjection to interpretation	1	NA
MWH	management of medical waste should be based on sound scientific evidence	2	NA
MWH	OSHA Bloodborne pathogen standard should be used a basis for the regulation	3	150
MWH	the regulations need to be more clearly written, and more specific	4	NA
JAM	current regulations are vague, confusing, and subjection to interpretation	1	NA
JAM	management of medical waste should be based on sound scientific evidence	2	NA
JAM	OSHA Bloodborne pathogen standard should be used a basis for the regulation	3	150
JAM	the regulations need to be more clearly written, and more specific	4	NA
API	management of medical waste should be based on sound scientific evidence	1	NA
API	infection from wastes other than sharps is non-existent	2	NA
API	what constitutes regulated medical waste should be clearer and not left open to interpretation	3	150
API	clarify requirement for disposal of diapers and sanitary napkins	4	130D1
API	define what is a small amount of body fluid or blood	5	130D2
API	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	6	NA
API	current regulations are not effective because they are vague, subject to interpretation, and result in unjustified expense	7	NA
API	other states regulations should be used to develop regulations that are less burdensome	8	NA
API	the regulations need to be more clearly written, and more specific	9	NA
ADC	management of medical waste should be based on sound scientific evidence	1	NA
ADC	infection from wastes other than sharps is non-existent	2	NA
ADC	what constitutes regulated medical waste should be clearer and not left open to interpretation	3	150
ADC	clarify requirement for disposal of diapers and sanitary napkins	4	130D1
ADC	define what is a small amount of body fluid or blood	5	130D2
ADC	increases in costs borne by hospitals for disposal have not produced comparable benefits to the environment	6	NA
ADC	current regulations are not effective because they are vague, subject to interpretation, and result in unjustified expense	7	NA

ADC	other states regulations should be used to develop regulations that are less burdensome	8	NA
ADC	the regulations need to be more clearly written, and more specific	9	NA
AWI	regulations are effective and materials regulated do not require modification	1	NA
AWI	the regulations mesh well with other regulations, but do need some updating	2	NA
AWI	regulations are redundant and inconsistent within themselves, and with other bodies of regulations	3	NA
AWI	regulations require reorganization and clarification	4	NA
AWI	regulations need to be consistent with other regulations	5	NA
AWI	definition of regulated medical waste needs to be reviewed	6	150
AWI	definition of storage should be modified to be consistent with federal transportation definition which preempts the DEQ definition	7	10
AWI	delete exemptions inconsistent with federal transportation standards	8	120.5
AWI	delete article 3 of Part IV - Packaging and labeling requirements, due to inconsistency with federal transportation standards	9	part IV article 3
AWI	delete or revise records to be maintained because certifications are inconsistent with federal transportation standards	10	310B
AWI	delete criteria that is inconsistent with federal transportation standards. 450 - packaging, labeling, placarding 500 - transport using reusable carts or containers 51	11	450, 500, 510
AWI	regulations should be consistent with other regulations including the ones listed in this comment	12	NA
AWI	internal references need to be updated using the VAC format	13	NA
AWI	revise language for exclusion in this section	14	130C2
AWI	handling of diapers and sanitary napkins should be consistent with existing OSHA standards	15	130D1
AWI	containment and cleanup procedures should be modified language regarding personal protective equipment should be modified	16	280A
AWI	section regarding air emissions should defer to federal standards	17	530
AWI	review section requiring shredding of steam sterilized wastes	18	Part VIII
AWI	this points out certain publications that should be used to evaluate alternate treatment technologies	19	Part IX
AWI	although the regulations say that conformance with the conditions are sufficient to establish a permit-by-rule the department requires acknowledgment that conditions have been fulfilled	20	690D
AWI	reorganize Part X and eliminate waste supply analysis in 730D	21	Part X
AWI	reusable container management, spill cleanup procedures are set out in several location and are redundant	22	260
AWI	the model regulation from the Medical Waste Institute is recommended as a guide for Virginia's regulation	23	NA