

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

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FILED

SEP 10 2 13 PM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Form #3

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Division of Health, Department of Health and Human Resources TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §§20-5J-6a and 22-18-7(d)

AMENDMENT TO AN EXISTING RULE: YES X NO

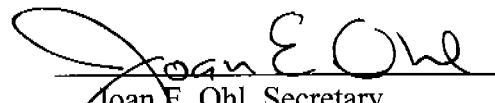
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 56

TITLE OF RULE BEING AMENDED: Infectious Medical Waste

IF NO, SERIES NUMBER OF RULE BEING PROPOSED:

TITLE OF RULE BEING PROPOSED:

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.


Joan E. Ohl, Secretary

\$14.40

**SUMMARY OF THE
INFECTIOUS MEDICAL WASTE RULE (64 CSR 56)
AND PROPOSED AMENDMENT**

The rule regulates the management of infectious medical waste within the state. This rule mandates the processes that generators of infectious medical waste must follow in the handling, processing, storing, treating, and disposing of their infectious waste. It also mandates the procedures that transporters of infectious waste must follow for the proper management of transported wastes.

This amendment of the rule adds a public participation procedure for noncommercial facilities in compliance with East End Ass'n v. McCoy, 198 W. Va. 458, 481 S.E.2d 764 (1996). It also adds the necessary language to make this rule compliant with West Virginia Code § 20-5K-3 that established a process for a referendum on siting commercial infectious medical waste treatment facilities. A fee is also added for the review of alternative treatment technologies.

The rule has been renumbered in accordance with the Secretary of State's current numbering system and to accommodate new material.

INFECTIOUS MEDICAL WASTE, 64 CSR 56

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

The proposed amendment of the rule was undertaken to comply with East End Ass'n v. McCoy, 198 W. Va. 458, 481 S.E.2d 764 (1996) by adding a public participation requirement in the rule for non-commercial large quantity infectious medical waste management facilities. It also was an opportunity to make the rule compliant with the requirements of W. Va. Code Chapter 20, Article 5K, related to commercial siting.

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: September 8, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 265, Charleston, WV 25305

Telephone: 558-3223

LEGISLATIVE RULE TITLE: Infectious Medical Waste, 64 CSR 56

1. Authorizing statute(s) citation: WV Code §§ 20-5J-6(a), and 22-18-7(d).
Related - W. Va. Code §§ 20-5J-1 et seq., 20-5K-1 et seq., and 22-18-1 et seq.
2.
 - a. Date filed in State Register with Notice of Hearing or Public Comment Period:
July 22, 1998
 - b. What other notice, including advertising, did you give of the hearing?
A press release announced the availability of the proposed rule.
Notification was made by mail to each facility under permit. The proposed rule and notice were sent to the committee who helped draft the changes
 - c. Date of Public Hearing(s) or Public Comment Period ended:
August 21, 1998

- d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X

No comments received

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

September 10, 1998

- f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule (please type):

Larry Arnold, Attorney, Office of General Counsel

Dept. of Health and Human Resources, Room 265, Capitol Complex

Charleston, West Virginia 25305

558-3223 FAX: 558-1130 LArnold@WVDHHR.ORG

- g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule (please type):

Joe Wyatt, Assistant Director / Infectious Medical Waste

Office of Environmental Health Services

815 Quarrier St., Suite 418

Charleston, WV 25301 558-2981

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place a hearing for the taking of evidence and a general

description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefore?

N/A

e. Attach findings and determinations and reasons:

Attached N/A

FISCAL NOTE FOR PROPOSED RULES

Rule Title:

Type of Rule: ☒ Legislative ☐ Interpretive ☐ Procedural

Agency: Division of Health
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$	\$
Personal Services					
Current Expense					
Repairs & Alterations					
Equipment					
Other					
Revenue				1,000	1,000

2. Explanation of above estimates.

Revenue: Alternative Treatment Evaluation Fee 2 @ \$500.00

3. Objectives of this rule:

The objective of this rule is to properly manage the generation, storage, transfer and treatment of Infectious Medical Waste.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

Minimal

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

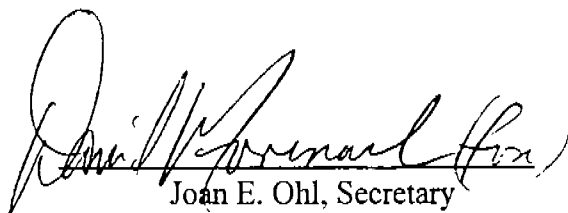
Developers of alternative treatment technologies will be charged a one time \$500.00 evaluation fee. The program reviews one or two such technologies per year.

C. Economic Impact on Citizens/Public at Large.

None

Date: 7/22/98

Signature of Agency Head or Authorized Representative

A handwritten signature in black ink, appearing to read "Joan E. Ohl", is written over a horizontal line.

Joan E. Ohl, Secretary

Department of Health and Human Resources

Infectious Medical Waste

Commenters

Paul T. Kuryla, M.D.	Dunbar Medical Associates
Tom Degen	West Virginia Environmental Council
Julie Pratt	The East End Association
Kathy Winkler	Mercer County Citizens Action Alert
Rachel Belcher	Mercer County Citizens Action Alert
David Perkins	Camden Clark Memorial Hospital
Cathy Slempp	Bureau for Public Health - Division of Surveillance and Disease Control
Jim Kranz	West Virginia Hospital Association
Alan Ducatman	WVU School of Medicine

**Responses to Comments
and
Changes Made as a Result of the Public Comment Period**

A public comment period on the proposed rule, Infectious Medical Waste, 64 CSR 56, was held beginning July 22, 1998, and ending on August 21, 1998. The comments are summarized below, and the Department's responses and changes to the rule are detailed.

Comment: "We are concerned that if compliance is met with the new amendment #64 W. Va. Code §§ 20-5J-6(a) & 22-18-7(d). This will cause us to be out of compliance with Federal OSHA Regulations."

"Our area of concern lies in the proper disposal of medical waste such as disposable speculums, GYN brushes, paddles, table paper soiled with body fluids. We feel that disposal of such waste as mentioned above in our regular landfill trash may pose a threat to housekeepers and etc. when removing said trash to dumpsters."

Response: W. Va. Code Chapter 20, Article 5J mandated the promulgation of the West Virginia Infectious Medical Waste Rule. W. Va. Chapter 22 is the solid waste law. The Federal OSHA regulations related to the Infectious Medical Waste Rule is most likely 29 C.F.R. §1910.1030, Bloodborne pathogens.

In the Bloodborne pathogens regulation, the definition of "Regulated Waste" is:

liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

To completely understand this definition it is necessary to look at the definition in the Bloodborne pathogens regulation of "Other Potentially Infectious Materials": namely;

(1) The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, and body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and HIV-containing cell or tissue cultures, organ cultures; and

(3) HIV-or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

In section 3.2 of the Infectious Medical Waste Rule, the definition of Blood and Blood Products is: "Liquid waste human blood and blood products in a free-flowing or unabsorbed state."

The Infectious Medical Waste Program considers any item that is contaminated with blood or one of the body fluids, listed as other potentially infectious materials, which can be dislodged during normal handling to be infectious medical waste. It is the Infectious Medical Waste Program's opinion that these respective definitions of the OSHA regulation and the Infectious Medical Waste Rule do not conflict.

§ 11.10.a. Comment: "[A]fter the word 'secretary' insert the words 'of State.' This will make the language consistent with WV Code §20-5K-3(b)(1). . . ."

Response: This change was made.

§ 11.12 Comment: "[A]fter the words 'in these regulations.' The words 'or on applications forms prescribed by the secretary' seem redundant, I assume they are the result of a word processing error. Another way of reading it would be that the agency can amend the rule by changing the application forms. I don't remember that the committee agreed to this. It is my understanding that the committee wanted all requirements reflected in the rule, so that there would be no misunderstanding or confusion regarding the application process."

Response: It is redundant, and the phrase "or on applications forms

prescribed by the secretary" was eliminated.

§§11.12.b and 11.12.c. Change: The requirements concerning applications for infectious medical waste management facilities did not contain a requirement for a social security number as required by West Virginia Code § 16-1-18a. The requirement for social security numbers was added.

Comment: "Russ Rader stated that it is the agency's position that permits are not transferable or assignable. The committee agreed to this, and the addition of 4.18 on page 12 was made to reflect this position. The portion of the rule concerning commercial facilities does not reflect this position, which constitutes a significant inconsistency in the rule. The following changes make that position consistent throughout the rule: . . ."

§11.13.d.6. Comment: "[D]elete 11.13.d.6. which reads 'The permit is to be transferred to a new owner or operator,' This will require renumbering the rest of 11.13.d."

Response: Paragraph 11.13.d.6. was eliminated, and the remainder of the subdivision was renumbered.

§11.15 Comment: "[D]elete the entire subsection 11.15. 'Transfer of Permit' and replace it with the following:"

"11.15 Permits issued by the secretary shall not be transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. A person seeking to succeed to the rights granted by a permit shall file a new permit application with the secretary."

Response: Permits should not be transferrable, and the proposed rule has been modified. Subsection 4.18 prohibits the transfer of a non-commercial permit, but it provides a mechanism for operation while a new permit is issued. These same provisions are included in the commercial process to avoid inconsistencies in the rule as follows:

11.15. Transfer of Facility.

11.15.a. Permits issued by the secretary are not transferable or

assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. An existing commercial facility that changes ownership may, however, continue to operate under the previous owner's permit conditions until such time as the secretary can process the new permit application required by this section, provided the new owner sends the secretary a letter in which the new owner:

11.15.a.1. Advises the secretary of such change of ownership including any management changes; and

11.15.a.2. Agrees to be bound by the conditions and policies established in the infectious medical waste management plan for that facility by the previous owner until such time as a new management plan can be approved by the secretary.

§11.17.a. Comment: "[A]fter the words 'major modification' delete the words 'or permit transfer.'"

Response: The words "or permit transfer" were eliminated.

§11.17.a.4.I. Comment: "[A]fter the words 'major modification' delete the words 'and permit transfers.'"

Response: The words "and permit transfers" were deleted.

§11.18.a. Comment: "[A]fter the words 'new facility' delete the words 'transfer of an existing permit.'"

Response: The words "transfer of an existing permit" were removed.

Other necessary changes were made in format, style and numbering, and non-substantive clarifying changes were made.

Dunbar Medical Associates

Family Practice • Internal Medicine

1100 Grosscup Avenue • Dunbar, WV 26064 • (304) 768-8811
3701 Tays Valley Road • Suite D • Hurricane, WV 25526 • (304) 757-3131

JOHN V. MERRIFIELD, M.D.

JOHN P. LILLY, M.D.

PAUL T. KURYLA, M.D.

JONATHAN P. LILLY, M.D.

MATTHEW B. UPTON, M.D.

JOHN W. NEVILLE, M.D.

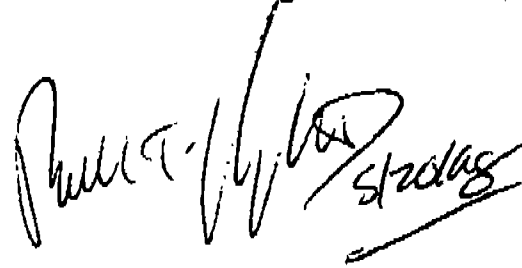
JEFFREY E. HOLMES, M.D.

Physicians at DMA would like to take this opportunity to voice our comment on proposed rule title #64 W.Va. code ss 20-5j-6(a), & 22-18-7(d).

We are concerned that if compliance is met with the new amendment #64 W.Va. code ss 20-5J-6(a), & 22-18-7(d). This will cause us to be out of compliance with Federal OSHA Regulations.

Our area of concern lies in the proper disposal of medical waste such as disposable speculums, GYN brushes, paddles, table paper soiled with body fluids. We feel that disposal of such waste as mentioned above in our regular land fill trash may pose a threat to housekeepers and etc. when removing said trash to dumpsters.

to



RECEIVED
58 AUG 21 PM 1:28
OFFICE OF THE SECRETARY
WV DEPARTMENT OF HEALTH & HUMAN SERVICES
1000 MARSHALL STREET
CHARLESTON, WV 25309

TOM DEGEN

P.O. Box 83 • Chloco, WV 25235 • phone/fax (304) 655-8651 • TDegen@wwwise.org

FAX COVER SHEET

To: Marsha Dadisman, Acting Director, Regulatory Development or
Larry Arnold
Department of Health & Human Resources
Capitol Complex, Building 3, Room 265
Charleston, WV 25305

Re: Comments on 65 CSR 56 Infectious Medical Waste Rule

From:

Tom Degen

Pages (Including Cover) 10 Date August 21, 1998

If You Do Not Receive All Pages, Please Call 655-8651

Hard Copy to Follow on request

Please note that all replies received are attached. For those that returned my letter signed, I have only attached the last page, in order to save phone time and paper.

Tom Degen

THANK YOU

TOM DEGEN

P.O. Box 83 • Chloe, WV 25235 • phone/fax (304) 655-8651 • TDegen@wvwise.org

August 9, 1998

Members of the Infectious Medical Waste Advisory Committee:

As you know, the rule that we worked on for approximately a year is out for comment. I am uncomfortable offering comments to the rule on my own, as it may be perceived that I am not honoring the consensus that the committee reached.

However, I have some concerns that I think reflect the consensus of the committee, but were not included in the rule. To that end, I am circulating this among the members, hoping that the committee will sign onto these comments and offer them as committee comments.

1) The rule was not filed in time to be assured a place on the agenda of the Legislative Rule Making Review Committee (LRMRC). It was my distinct understanding that this rule would be filed as a legislative rule this summer in time for consideration by the 1999 Legislature. The LRMRC can consider the rule during the 1998 interims if it so desires, but I believe that this committee, in conjunction with Commissioner Taylor, Russ Rader, and perhaps Secretary Ohl, would have to bring it to the LRMRC's attention. There are good reasons for the LRMRC to consider the rule during the 1998 interims:

- This committee worked hard and in good faith to develop this rule revision, which Commissioner Taylor, in his April 15 letter to members of the committee, described as "... a model that can be used in other areas of the Bureau for Public Health.";
- The portion of the rule that addresses commercial facilities is needed to implement the provisions of S.B. 409, which was passed during the 1997 Legislative session. There have been proposals for commercial infectious medical waste facilities since the passage of this bill, and the rule provisions are necessary to give direction to those that may be authorized to proceed by the referendum provided for in S.B. 409; and
- The portion of the rule addressing noncommercial facilities was required by order of the West Virginia Supreme Court.

2) Russ Rader stated that it is the agency's position that permits are not transferable or assignable. The committee agreed to this, and the addition of 4.18. on page 12 was made to reflect this position. The portion of the rule concerning commercial facilities does not reflect this position, which constitutes a significant

inconsistency in the rule. The following changes make that position consistent throughout the rule:

On page 35, under subsection 11.13. "Modifications," delete 11.13.d.6. which reads "The permit is to be transferred to a new owner or operator;" This will require re-numbering the rest of 11.13.d.

On page 39, 11.17.a. after the words "major modification" delete the words "or permit transfer."

On page 40, 11.17.a.4.I. after the words "major modification" delete the words "and permit transfers."

On page 41, 11.18.a. after the words "new facility" delete the words "transfer of an existing permit."

Beginning on page 37, and running into page 38, delete the entire subsection 11.15. "Transfer of Permit" and replace it with the following:

11.15. Permits issued by the secretary shall not be transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. A person seeking to succeed to the rights granted by a permit shall file a new permit application with the secretary.

3) My next concern appears on page 31, subsection 11.12. after the words "in these regulations." The words "or on application forms prescribed by the secretary" seem redundant, I assume they are the result of a word processing error. Another way of reading it would be that the agency can amend the rule by changing the application forms. I don't remember that the committee agreed to this. It is my understanding that the committee wanted all requirements reflected in the rule, so that there would be no misunderstanding or confusion regarding the application process.

4) Finally, on page 30, subsection 11.10.a. after the words "secretary" insert the words "of state." This will make the language consistent with WV Code §20-5K-3(b)(1), the last sentence of which reads:

The secretary of state shall prescribe the form of the petition which shall include the printed name, address and date of birth of each person whose signature appears on the petition.

This is a technical change, since the rule must reflect the language in the Code.

I would appreciate hearing from each of you. If my understanding of the committee consensus is different from yours, or if you have any other questions or comments concerning this, please contact me. If you are agreeable to these changes, please sign the letter and return it to me. I will make copies and get them to Commissioner Taylor and Marsha Dadianan.

In closing I want to let you know that I found participating in this committee's work to be a rewarding experience. The sharing of perspectives and the resulting

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DEGEN

PAGE 02

cooperative effort has broadened my understanding of the issues involved, and if the committee should decide at some future time to continue to develop other aspects of infectious medical waste issues, I would be glad to participate.

Sincerely,


Tom Degen

cc: Jim Kranz
Lillian Morris
Alan Ducatman
David Perkins
Kathy Winkler
Dr. Henry Taylor
Rachel Belcher
Norm Steenstra
Russ Rader
Cathy Slempp
Julie Pratt
Pamela Payne
Joseph Wyatt

Julie Pratt

1544 Lee Street Charleston WV 25311
(304) 344-1673 * 342-9992 (fax) * Jpratt1@aol.com

FAX TRANSMISSION

TO Tom Degen
FROM Julie Pratt
DATE August 11 1998
PAGES: 1 (including cover)

I received your letter dated August 9th and am in agreement with the four changes you proposed to the infectious medical waste regulations that are currently out for public comment. It was my understanding as well that all permits, commercial and non-commercial, were to be non-transferable. I would also urge the Legislative Rule Making Review Committee to act on the regulations during the 1999 session, due to the pressing need to have up-to-date rules that reflect recent laws and court orders.

Thanks for all your work on this

08/21/98 12:15

DHHR - OFFICE OF THE SECRETARY → WV ENVIRONMENTAL

NO.083 P007/011

08/21/1998 11:39

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PAGE 04

08/13/1998 22:51

3044071195

MCCAA

PAGE 02

Land
Air
Water



MERCER COUNTY CITIZENS ACTION ALERT, INC.
144 Willowbrook Road
Princeton, WV 24740
(304) 425-5006

August 11, 1998

Dear Tom,

Thank you for your letter of August 9, 1998. As committee members, we are in complete agreement with comments 1-4 of that letter, as they reflect those decisions discussed and agreed to during the meetings of the committee over the past year.

We ask that you please submit this statement as evidence of our support for the comments set forth in the attached letter.

Sincerely,

Kathy Winkler
Kathy Winkler

Rachel Belcher
Rachel Belcher

cooperative effort has broadened my understanding of the issues involved, and if the committee should decide at some future time to continue to develop other aspects of infectious medical waste issues, I would be glad to participate.

Sincerely,


Tom Degen

cc: Jim Kranz

Lillian Morris

Alan Dusatman

David Perkins ———

Kathy Winkler

Dr. Henry Taylor

Rachel Belcher

Norm Steenstra

Russ Rader

Cathy Slemm

Julie Pratt

Pamela Payne

Joseph Wyatt

David Perkins 8/13/98

Printed by:
Title: Memo on rules

Friday, August 14, 1998 8:20:19 AM
Page 1 of 1



Wednesday, August 12, 1998 10:27:56 AM
Message



From: Cathy Slemp <cathy@bph.wvdhhr.org>, Internet
Subject: Memo on rules
To: Tom Degen

Thanks for your memo on the IMW rules developed through our committee. Not being able to hear the full discussions around final drafting of this rule due to other commitments, I can probably not provide substantive responses to many of your suggestions; However, I certainly do concur with the need for timely filing of this rule. It was my understanding that this rule was emergency filed, putting it into effect once the emergency filing was ruled upon by the Secretary of State. (It would probably also have been filed with the LRMRC for eventual passage through the standard route as well, for the enactment under emergency filing is time limited.) Dr. Taylor or the Office of Environmental Health Services could confirm this information and provide you with the current status of this filing. This may be information you already know. If so, my apologies.

--- Internet Message Header Follows ---

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Received: from DHHR-Message_Server by wvdhhr.org
with Novell_GroupWise; Wed, 12 Aug 1998 11:44:36 -0400
Message-Id: <s5d18024.036@wvdhhr.org>
X-Mailer: Novell GroupWise 5.2
Date: Wed, 12 Aug 1998 11:27:56 -0400
From: "Cathy Slemp" <cathy@bph.wvdhhr.org>
To: TDegen@wvwise.org
Subject: Memo on rules
Mime-Version: 1.0
Content-Type: text/plain; charset=US-ASCII
Content-Transfer-Encoding: quoted-printable
Content-Disposition: inline



**WEST VIRGINIA UNIVERSITY
SCHOOL OF MEDICINE**

August 19, 1998

Ms. Kathy Winkler
Mr. Tom Degen
Mercer County Citizens Action Alert
Fax: 304-487-1195

RE: Infectious Medical Waste Proposed Rule

Dear Ms. Winkler & Mr. Degen:

Thank you for alerting me to this issue.

As you know, Dr. Taylor asked me to play an advisory role to citizen and hospital representatives. I played less of a role in the crafting of proposed rule-making and actual language, as that is not my expertise.

1. I have a distinct impression that the committee intended for the proposed rule to go forward this year. Certainly, the need to respond to hospital needs and citizen concerns is immediate.
2. I did not participate in the discussion concerning transferability, but I am very sure that citizens expressed repeated concerns about the backgrounds, histories, and ethical business practices of some operators interested in the field. Whether perception or reality, if these concerns are to be addressed, non-transferability is preferable.
3. When I was present, the committee was clear that the application forms should flow from the rule, not vice-versa.

I hope this response is helpful.

Sincerely,

Alan Ducatman forw

Alan M. Ducatman, MD, MSc
Professor of Medicine
Chair, Department of Community Medicine

AMD/crw

Institute of Occupational and Environmental Health

Joint Health Science Center PO Box 9140 Morgantown WV 26505-9140 Telephone 304 293-2693 FAX 304 293 2639
Equal Opportunity / Affirmative Action Institution

**TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 56
INFECTIOUS MEDICAL WASTE**

**AGENCY APPROVED PROPOSED RULE
FILED FOR REVIEW BY THE
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

64 CSR 56

**TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 56
INFECTIOUS MEDICAL WASTE**

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TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH

SEP 10 2 14 PM '98

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

SERIES 56
INFECTIOUS MEDICAL WASTE

§64-56-1. General.

1.1. Scope. -- This legislative rule establishes requirements regarding the generation, handling, storage, transportation, treatment and disposal of infectious medical waste.

1.2. Authority. -- W. Va. Code §§20-5J-6(a) and ~~20-5E-7(d)~~ 22-18-7(d). Related - W. Va. Code §§20-5J-1 et seq., ~~and 20-5E-11, 12, 13, 14, 15, 16, and 17~~ 20-5K-1 et seq., and 22-18-1 et seq.

1.3. Filing Date -- ~~June 11, 1993.~~

1.4. Effective Date -- ~~June 11, 1993.~~

1.5. Preamble.

It is the intent of the department of health and human resources to provide effective controls for the management of infectious medical waste to ensure the protection of public health, safety and welfare and the environment, consistent with legislative policy stated as follows in W. Va. Code §20-5J-2:

"The Legislature finds that the proper and environmentally-sound disposal of medical waste and infectious and noninfectious medical waste is an important issue facing all West Virginians.

The Legislature further finds that effective controls for the management of medical waste are necessary to ensure the protection of the public health, safety and welfare, and the environment.

The Legislature further finds that regulation of the generation, handling, storage, transportation, treatment and disposal of medical waste is an important and necessary function of state government.

The Legislature further finds that toxic pollutants emitted by medical waste incinerators are an important public health hazard.

The Legislature further finds that commercial incineration of medical waste, and

its transportation in the infectious state, pose a potentially serious threat to the health, safety and welfare of West Virginians.

The Legislature further finds that safe and cost-effective alternatives to the incineration of infectious and noninfectious medical waste should be encouraged.

The Legislature further finds that the public interest is best served by:

- (1) Efforts to reduce the volume of medical waste generated at all levels;
- (2) On-site separation and treatment of infectious medical waste;
- (3) Treatment and disposal of infectious medical waste in local infectious medical waste management facilities; and
- (4) Treatment and disposal in approved regional infectious waste management facilities when administrative proceedings result in a finding that on-site or local treatment of infectious medical waste is not feasible.

The Legislature further finds that local responsibility for the minimization in volume, and for the treatment and disposal of infectious and noninfectious medical waste is an important part of a sound and rational waste management program.

The Legislature further finds that small quantity generators of infectious medical waste should either render such waste noninfectious on-site, or properly label and package the waste for transportation to a local infectious waste management facility for proper treatment and disposal.

The Legislature further finds that generators of medical waste should be informed and educated in its management; that training should be provided to all workers likely to come in contact with medical waste, including in-home health care workers; and that relevant information on the potential for infection and disease related to medical waste should be made available to the general public, including in-home health care patients.

The Legislature further finds that the necessity for transporting infectious medical waste be minimized, and that any infectious medical waste transported be safely packaged and identified by source and content.

The Legislature further finds that public policy favors a reduction in the volume of infectious and non-infectious medical waste, the separation of infectious medical waste from noninfectious medical waste, and that efforts to reduce medical waste should be fostered and strongly encouraged at all levels of generation.

The Legislature further finds that noninfectious medical waste is solid waste.

The Legislature further finds that noninfectious medical waste should be handled by environmentally sound disposal technologies, and that alternative disposal technologies promoting safe recycling and limiting the need for incineration should be emphasized, developed and utilized.

Therefore, it is the policy of the State of West Virginia to prohibit commercial infectious medical waste facilities; to regulate and control the generation, handling, storage, transportation, treatment and disposal of infectious and noninfectious medical waste; to reduce the generation of infectious and noninfectious medical waste; to encourage local responsibility for the minimization, management and disposal of infectious and non-infectious medical waste; and to authorize the department of health and human resources to promulgate rules and regulations necessary to carry out the purposes of this article."

§64-56-2. Applicability; Exemptions; Enforcement.

2.1. Applicability.

This rule applies to: any person who generates, handles, stores, transports, treats or disposes of infectious medical waste, or who proposes to do so, except as specified in Section 2.2 of this rule; commenters on applications for infectious medical waste management facilities; county commissions; the secretary of state; and the secretary of the department of health and human resources.

2.2. Exemptions.

2.2.a. Individual households in which infectious medical waste is generated by a member of the household during self health care or by the provision of health care services within the residence shall be exempt from the requirements of this rule, except that the householder shall place sharps in a container with a high degree of puncture resistance prior to discarding them.

2.2.b. Ambulance or rescue services shall be exempt from the requirements of this rule, except that all infectious medical waste generated in an ambulance or rescue vehicle shall be packaged as required by Section 6.2 of this rule and delivered to a permitted infectious medical waste management facility.

2.3. Enforcement.

This rule is enforced by the secretary of the state department of health and human resources.

§64-56-3. Definitions.

3.1. Animal Carcasses, Body Parts, Bedding and Related Wastes. -- Contaminated animal carcasses, body parts, and bedding of animals that are known to have been exposed to infectious agents during research, production of biologicals, testing of pharmaceuticals, or for any other reason.

3.2. Blood and Blood Products. -- Liquid waste human blood and blood products in a free-flowing or unabsorbed state.

3.3. Commercial Infectious Medical Waste Facility. -- Any infectious medical waste management facility at which thirty-five per cent (35%) or more by weight of the total infectious medical waste stored, treated, or disposed of by said facility in any calendar year is generated off-site.

3.4. Cultures and Stocks of Microorganisms and Biologicals. -- Discarded cultures, stocks, specimens, vaccines and associated items likely to have been contaminated by an infectious agent, discarded etiologic agents, and wastes from the production of biologicals and antibiotics likely to have been contaminated by an infectious agent.

3.5. Disposal. -- The discharge, deposit, injection, dumping, spilling, leaking or placing of any infectious medical waste into or on any land or water so that such infectious medical waste, or any constituent thereof, may be emitted into the air, discharged into any waters, including groundwater, or otherwise enter into the environment. (See Section 5.7 of this rule.)

3.6. Generator. -- Any person, by site location, whose act or process produces infectious medical waste.

3.7. Hospital. -- An institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons or services for the rehabilitation of injured, disabled or sick persons. This term also includes psychiatric and tuberculosis hospitals.

3.8. Infectious Agent. -- Any organism such as a virus or a bacteria that is in such quantity that it is capable of being communicated by invasion of and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

3.9. Infectious Medical Waste. --

3.9.a. Infectious medical waste is medical waste which is capable of producing an infectious disease. Medical waste shall be considered capable of producing an infectious disease if it has been, or is likely to have been, contaminated by an organism likely to be pathogenic to healthy humans, if such organism is not routinely and freely available in the community, and such organism has a significant probability of being present in sufficient quantities and with sufficient virulence to transmit disease.

3.9.b. For the purposes of this rule, infectious medical waste includes the following

materials:

3.9.b.1. Cultures and stock of microorganisms and biologicals;

3.9.b.2. Blood and blood products;

3.9.b.3. Pathological wastes;

3.9.b.4. Sharps;

3.9.b.5. Animal carcasses, body parts, bedding and related wastes;

3.9.b.6. Isolation wastes;

3.9.b.7. Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious medical waste; and

3.9.b.8. Waste contaminated by or mixed with infectious medical waste.

3.9.c. For the purposes of this rule, infectious medical waste does not include the following materials:

3.9.c.1. Human remains and body parts being used or examined for medical purposes which are under the control of a licensed physician or dentist and are not abandoned materials;

3.9.c.2. Human remains lawfully interred in a cemetery or in preparation by a licensed mortician for interment or cremation;

3.9.c.3. Used personal hygiene products, such as diapers, facial tissues and sanitary napkins;

3.9.c.4. Gauze and dressing material, containing small amounts of blood or other body secretions with no free flowing or unabsorbed liquid;

3.9.c.5. Hair, nails, and extracted teeth;

3.9.c.6. Waste generated by veterinary hospitals, except for waste meeting the criteria found in Sections 3.9.b.1, 3.9.b.4, or 3.9.b.5 of this rule; and

3.9.c.7. Medical tubing and devices with a signed and dated certification by the facility which states: "I hereby certify under penalty of law that this waste has not been contaminated with infectious medical waste, as defined in Infectious Medical Waste, 64 CSR 56."

3.9.d. Infectious medical waste contaminated with radioactive waste is considered to be

radioactive waste and is subject to State and federal law and regulation as radioactive waste.

3.9.e. Infectious medical waste contaminated with hazardous chemical waste is considered to be hazardous chemical waste and is subject to State and federal law and regulation as hazardous chemical waste.

3.10. Infectious Medical Waste Management Facility. -- An infectious medical waste facility which generates, handles, processes, stores, treats or disposes of infectious medical waste, including all land and structures, other appurtenances, and improvements thereon, used for infectious medical waste.

3.11. Isolation Wastes. -- Wastes generated from the care of a patient who has or is suspected of having any disease listed as Class IV in "Classification of Etiologic Agents on the Basis of Hazard," published by the United States Centers for Disease Control.

3.12. Manifest. -- The form used for identifying the quantity, composition, and the origin, routing, and destination of infectious medical waste during its transportation from the point of generation to the point of off-site treatment or disposal.

3.13. Medical Waste. -- Infectious and noninfectious solid waste generated in the course of the diagnosis, treatment or immunization of human beings or animals, or in research pertaining thereto, or in the production or testing of biologicals. The term "medical waste" does not include low-level radioactive waste, any hazardous waste identified or listed under Subtitle C, or any household waste as defined in the regulations promulgated pursuant to Subtitle C.

3.14. Non-commercial Infectious Medical Waste Facility. -- Any infectious medical waste facility at which less than thirty-five per cent (35%) by weight of the total infectious medical waste stored, treated or disposed of by said facility in any calendar year is generated off-site.

3.15. Noninfectious Medical Waste. -- Any medical waste not capable of producing an infectious disease or infectious medical waste which has been rendered noninfectious. Noninfectious medical waste is considered solid waste for purposes of this rule.

3.16. Off-Site. -- A facility or area for the collection, storage, transfer, processing, treatment, or disposal of infectious medical waste which is not on the generator's site, or a facility or area that receives infectious medical waste for storage or treatment that has not been generated on-site at that facility or area.

3.17. On-Site. -- The same or geographically contiguous property which may be divided by a public or private right-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing, as opposed to going along, the right-of-way. Non-contiguous properties owned by the same person but connected by a right-of-way controlled by said person and to which the public does not have access, is also considered on-site property. Hospitals with more than one (1) facility located in the same county shall be considered one (1) site.

3.18. Pathological Waste. -- Human pathological wastes, including tissues, organs, body parts, and containers of body fluids, exclusive of those fixed in formaldehyde or another fixative.

3.19. Person. -- Individual, partnership, corporation or other legal entity.

3.20. Secretary. -- The secretary of the department of health and human resources or his or her designee.

3.21. Sharps. -- Discarded articles that may cause punctures or cuts and that have been used in animal or human patient care or treatment, or in pharmacies or medical, research or industrial laboratories, including, but not limited to, hypodermic needles, syringes with attached needles, scalpel blades, lancets and broken glassware.

3.22. Small Quantity Generator. -- Any generator of infectious medical waste who generates fifty (50) pounds or less during a one (1) month period.

3.23. Storage. -- The containment of infectious medical waste on a temporary basis. Storage shall not constitute disposal of the waste. The containment of infectious medical waste during off-site transport is considered to be a form of storage.

3.24. Subtitle C. -- Subtitle C of the federal Resource Conservation and Recovery Act of 1976, 90 Stat. 2806, as amended.

3.25. Transport. -- The movement of infectious medical waste from one location to another, except for on-site movement of infectious medical waste.

3.26. Transporter. -- A person engaged in the off-site transportation of infectious medical waste.

3.27. Transport Vehicle. -- A motor vehicle, aircraft, boat, barge or rail car used for the transportation of cargo by any mode. Each cargo-carrying body shall be considered a separate transport vehicle.

3.28. Treatment. -- Any method, technique or process, including neutralization, designed to change the physical, chemical or biological character or composition of any infectious medical waste so as to render such waste noninfectious.

§64-56-4. General Permit Application and Approval Procedures for Non-Commercial Infectious Medical Waste Facilities.

4.1. This section applies only to non-commercial infectious medical waste facilities. ~~On or after the first day of October, one thousand nine hundred ninety-one,~~ No person may own, construct, modify or operate an infectious medical waste management facility, nor shall any person store, transport, treat or dispose of any infectious medical waste without first obtaining a

permit from the secretary, unless exempted by Sections 2.1, 2.2 or ~~4.15~~ 4.17 of this rule. ~~Provided, however, That submission of an application for a permit under this rule within forty-five (45) days after the effective date of this rule shall be a rebuttable presumption of compliance with this rule until such time as the secretary grants or denies the permit.~~

4.2. No person shall begin physical construction of a new non-commercial infectious medical waste management facility without having received a permit.

4.3. The owner of ~~an~~ a non-commercial infectious medical waste management facility shall be responsible for insuring that the facility has a permit.

4.4. The owner of an infectious medical waste facility shall provide public notice of intent to apply for a permit.

4.4.a. Public notice shall be given by the following methods:

4.4.a.1. By mailing a copy of a notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such requests; and

4.4.a.2. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

4.5. The applicant for a permit for a non-commercial infectious medical waste facility shall maintain a public participation file. This file shall contain a summary of all comments and responses received during the pre-application public notification phase by the facility. This file shall be submitted to the secretary by the applicant with the application.

4.6. An application for a permit shall be submitted to the secretary in duplicate on forms prescribed by the secretary and shall include the following:

4.6.a. The name, mailing address, and location of the facility, using latitude and longitude to the nearest second, for which the application is submitted;

4.6.b. The name, address and telephone ~~number~~ and fax numbers of the owner of the facility, and if the owner is an individual or a partnership, the social security number or numbers of the owner or partners;

4.6.c. The name, address and telephone ~~number~~ and fax numbers of the manager of the facility, if different from the owner; and if the manager is an individual or partnership different from the owner, the social security number or numbers of the individual or partners;

4.6.d. Two copies of the ~~A~~ proposed infectious medical waste management plan as

required by Section 5 of this rule; and

4.6.e. A copy of the public participation file.

4.7. For new non-commercial infectious medical waste management facilities, the application shall be accompanied by two (2) copies of a topographic map showing the facility and the area one thousand (1,000) feet around the facility site, which clearly shows the following:

4.7.a. The map scale and date;

4.7.b. Land uses (e.g., residential, commercial, agricultural, recreational);

4.7.c. The orientation of the map (north arrow);

4.7.d. The legal boundaries of the facility ~~site~~ with the latitude and longitude to the nearest second for the site;

4.7.e. Access control (fences, gates); and

4.7.f. Buildings to be used for treatment, storage, and disposal operations and other structures (e.g. recreation areas, run-off control systems, access and internal roads, storm, sanitary, and process sewerage systems, loading and unloading areas, fire control facilities).

4.8. The secretary shall not begin the evaluation of a permit before receiving a complete application, including any supplemental information requested under ~~Section 4.9~~ Section 4.10 of this rule. Within thirty (30) days, the completeness of a permit application shall be judged independently of the status of any other permit application or permit for the same facility or activity.

4.9. The secretary shall not issue a permit before receiving a complete application.

4.10. The secretary shall have the authority to request supplemental information needed to demonstrate that the facility will be operated in compliance with this rule.

4.11. When the secretary determines an application for a new non-commercial infectious medical waste facility or a major change to an existing facility to be complete, he or she shall instruct the applicant or permittee to give public notice.

4.11.a. Public comment shall be conducted in accordance with the following guidelines:

4.11.b. Public notice shall be given by the following methods:

4.11.b.1. By mailing a copy of a notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such requests; and

4.11.b.2. By publishing the public notice as a Class II legal advertisement in a qualified newspaper, as defined in W. Va. Code §59-3-1, serving the county where the facility will be located. That legal advertisement shall also be placed in newspapers of adjacent counties when a proposed facility is within two (2) miles of a county line. The cost of the publication will be the responsibility of the applicant who shall send a certification of publication to the secretary within twenty (20) days after publication; and

4.11.b.3. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

4.11.c. All public notices issued shall contain the following information:

4.11.c.1. The name and address of the office processing the permit action for which notice is being given;

4.11.c.2. The name and address of the permittee or permit applicant, and if different, of the facility or activity regulated by the permit;

4.11.c.3. A description of the activities covered in the application, including the type of technology that will be used to treat infectious medical waste, the types, amounts, and origins of infectious medical waste to be handled, site improvements, and infectious medical waste handling methods;

4.11.c.4. The name, address, and telephone and fax numbers of a person from whom interested persons may obtain further information;

4.11.c.4.A. The availability of the application shall include, but not be limited to, copies placed at the courthouse of the county in which the facility is to be located, the city or town hall of any municipal government within two (2) miles of the proposed location of the facility, and the primary public library in the county.

4.11.c.4.B. Copies of the application shall be available from the secretary at no cost.

4.11.c.5. A general description of the location of the proposed permit area including streams;

4.11.c.6. A clear and accurate location map. A map of a scale and detail found in the West Virginia official state highway map is the minimum standard for acceptance. The

map size shall be at a minimum two (2) inches by two (2) inches. Longitude and latitude lines and a north arrow shall be indicated on the map, and such lines will cross at or near the center of the proposed permit area;

4.11.c.7. A reference to the date of previous public notices relating to the permit;

4.11.c.8. That any interested person may submit a written comment on the application, and that such comments shall include a concise statement of the nature of the issues raised;

4.11.c.9. That any interested person may submit a written request for a public hearing, and that such request shall include a concise statement of the nature of the issues raised; and

4.11.c.10. That the secretary shall conduct a public hearing within forty-five (45) days in the county where the proposed facility is to be located whenever he or she receives a request.

4.11.d If any data, information or arguments submitted during the public comment period raise substantial new questions concerning the proposed major change or new facility, the secretary shall:

4.11.d.1. Reopen or extend the public comment period for thirty (30) days to give interested persons an opportunity to comment on the information or argument submitted; or

4.11.d.2. Require a public hearing.

4.11.e. In the event a public hearing is held:

4.11.e.1. Public notice of the hearing shall be given by the secretary at least thirty (30) days before the hearing;

4.11.e.2. A transcript of the hearing shall be available to the public from the secretary;

4.11.e.3. At the hearing, any person may make oral comments and submit written statements and data concerning the proposed major changes or new facility. Reasonable limits may be set on the time allowed for oral statements, and the written statements shall be submitted to the secretary no later than ten (10) days after the close of the hearing; and

4.11.e.4. The secretary shall act on the permit application within thirty (30) days after the date for the submission of written statements to the secretary.

4.11.f. In the event a public comment period is held, the secretary shall act on the permit application within thirty (30) days after the close of the comment period.

4.12. Permits shall be renewed annually prior to expiration. An application for permit renewal shall be submitted forty-five (45) days prior to the expiration date of the previous permit.

4.13. An application for an original or renewal permit shall be accompanied by a non-refundable application fee according to the schedule shown in Table 64-56A found at the end of this rule.

4.14. A permit shall be issued if the facility is, or in the case of a projected facility, is planned to be, in compliance with the applicable provisions of this rule and has submitted the application fee.

4.15. The secretary may refuse to grant or renew a permit if an applicant or permittee has attempted to obtain a permit by means of fraud, deceit or material misrepresentation or public comment reveals a situation which would endanger public health.

4.16. A permittee shall submit an application for approval of a major change in the permittee's infectious medical waste management plan before implementing the change. Minor changes in the infectious medical waste plan may be made without notifying the secretary and shall be included in the next application for permit renewal. All major changes shall be approved prior to implementation: Provided, however, That no prior approval is necessary in the case of a hospital in any instance in which, in the sole discretion and judgement of the hospital, an immediate change in any part of the infectious medical waste plan is required to protect the safety and care of patients, employees or the public. In such an event, the hospital will notify the secretary within fifteen (15) days of any changes to its plan. An application for approval of any change in the plan which is beyond the control of the permittee shall be submitted within fifteen (15) days of its occurrence. A major change consists of any of the following:

4.16.a. Installing a new unit for the treatment of infectious medical waste or replacing existing units not including repairs or improvements to existing units;

4.16.b. Changing the location of treatment; or

4.16.c. Permanently increasing the volume of infectious medical waste by at least twenty percent (20%), if the amount of the increase is fifty (50) pounds or more.

4.17. Small quantity generators who generate infectious medical waste in the provision of health care services in their own office are not required to obtain a permit. Small quantity generators shall keep their infectious medical waste management plan on file and shall make a copy available to the secretary on request.

4.18. Permits issued by the secretary for a non-commercial infectious waste facility are not transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. An existing large quantity generator that changes ownership, however, may continue to operate under the previous owner's permit conditions until such time as the secretary can process the new permit application required by this section, provided the new owner sends the secretary a letter in which the new owner:

4.18.a. Advises the secretary of such change of ownership including any management changes; and

4.18.b. Agrees to be bound by the conditions and policies established in the infectious medical waste management plan for that facility by the previous owner until such time as a new management plan can be approved by the secretary.

§64-56-5. Infectious Medical Waste Management Plan.

5.1. All infectious medical waste management facilities shall develop an infectious medical waste management plan. ~~Existing facilities which are small quantity generators shall develop a plan within ninety (90) days of the effective date of this rule.~~

5.2. The infectious medical waste management plan shall set forth policies and procedures for managing infectious medical waste which are consistent with this rule and shall include, at a minimum, the following:

5.2.a. A projection of the weight of the infectious medical waste which will be generated monthly;

5.2.b. A description of infectious and noninfectious medical waste handling, storage, separation and volume-reduction procedures;

5.2.c. The methods which will be used to treat the infectious medical waste;

5.2.d. Transportation method;

5.2.e. Manifest systems and labeling;

5.2.f. Disposal methods consistent with Section 10.4 of this rule;

5.2.g. The name, address, telephone ~~number~~ and fax ~~numbers~~ and public service commission or other permit or license number of any infectious medical waste transporter, if applicable;

5.2.h. Training procedures, including an outline of training programs, and procedures for the certification of personnel involved in the treatment of infectious medical waste;

5.2.i. The name, address and telephone ~~number~~ and fax numbers of the person responsible for infectious medical waste management at the generator or the facility, and the name, address and telephone ~~number~~ and fax numbers of an alternate person to contact in the event the manager is not available;

5.2.j. Policies requiring that no infectious medical waste will be knowingly transported or knowingly received by the generator or facility without being packaged and labeled in accordance with this rule;

5.2.k. Contingency plans for effective action to minimize damage from any interruption in treatment, storage or disposal of infectious medical waste;

5.2.l. A description of the procedures used to:

5.2.l.1. Prevent hazards in loading and unloading operations;

5.2.l.2. Prevent run-off from infectious medical waste handling areas to other areas of the facility or environment;

5.2.l.3. Prevent contamination of water supplies;

5.2.l.4. Mitigate effects of equipment failure and power outages; and

5.2.l.5. Prevent exposure of personnel to infectious medical waste;

5.2.m. Procedures for continuity of operations during a change of ownership;

5.2.n. Any other information pertinent to the evaluation of compliance with this rule.

5.3. Infectious medical waste management facilities which are willing to accept infectious medical waste generated off-site for treatment shall also include the following in their infectious medical waste management plan:

5.3.a. Procedures for receiving off-site infectious medical waste which are consistent with this rule;

5.3.b. A statement as to whether the facility plans to receive from off-site more than thirty-five (35) percent by weight of the total amount of infectious medical waste treated at the facility;

5.3.c. A statement that the facility will not knowingly accept any infectious medical waste which is not properly packaged and labeled in accordance with Section 6 of this rule;

5.3.d. Procedures for keeping records in accordance with Section 13 of this rule;

5.3.e. Procedures for returning manifests to the generator after treatment of the infectious medical waste;

5.3.f. Procedures for reporting to the secretary as required by this rule; and

5.3.g. Procedures to be followed for closure of the facility including, but not limited to, notification of all facilities using the treatment service thirty (30) days prior to closure.

5.4. The secretary may grant a period of no more than one (1) year from the date of issuance of final applicable United States Environmental Protection Agency rules relating to medical waste incineration standards for an infectious medical waste management facility which has been granted a waiver under Section 10.2.g of this rule to develop a proposal to modify or upgrade its treatment process to comply with this rule. The plan for modification or upgrading shall be considered to be part of the facility's infectious medical waste management plan.

5.5. The infectious medical waste management plan shall comply with this rule.

5.6. Infectious medical waste management facilities shall operate in compliance with their infectious medical waste management plan as approved by the secretary.

5.7. Disposal of untreated infectious medical waste in this State is prohibited.

§64-56-6. Packaging and Labeling.

6.1. General.

6.1.a. The generator of infectious medical waste shall be responsible for ensuring that the packaging and labeling of infectious medical waste is in compliance with this rule and any other applicable state or federal laws or regulations.

6.1.b. Contractors or other agents may provide services to the generator, including packaging and labeling of infectious medical waste: Provided, however, That no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the infectious medical waste as required by this rule. Nothing in this section shall be construed to prevent or limit any cause of action by a generator against any other party for any reasons for which the law gives a remedy.

6.1.c. No person shall knowingly accept for transportation, storage, treatment or disposal any infectious medical waste that is not packaged and labeled in accordance with this rule. Contractors or other agents may package or repackage infectious medical waste to comply with this rule, if the packaging or repackaging is performed prior to transportation off-site or storage on-site. Proper repackaging of infectious medical waste that has spilled during transportation is required prior to further transportation.

6.2. Packaging.

6.2.a. All infectious medical waste shall be packaged as required by this rule prior to storage, treatment, or transport.

6.2.b. Infectious medical waste shall be contained and sealed on-site in leak-proof plastic bags capable of passing the American Society for Testing and Materials drop weight test (ASTM-D-959-80) using one hundred twenty-five (125) pounds, or in three (3) mil plastic bags or containers with equivalent containment properties. Free liquids shall be contained in break-resistant, tightly stoppered containers. Heavier materials shall be supported in double-walled corrugated fiberboard boxes or equivalent rigid containers.

6.2.c. Sharps shall be collected at the point of generation in rigid, leak-proof and puncture-resistant containers clearly marked as infectious medical waste. Containers shall be compatible with selected treatment processes to preclude contact with waste materials, and sealed before handling. Sharps containers shall not be completely filled.

6.2.c.1. If the sharps are to be stored or treated off-site, the containers shall be placed inside a plastic bag as specified in Section 6.2.b of this rule. Prior to storage, the plastic bags shall be bound at the gathered open end with tape or another closing device that prevents leakage of liquids.

6.2.c.2. Sharps which are rendered noninfectious and encapsulated in a solid state on-site may be discarded as solid waste. The encapsulated container shall be labeled in accordance with Section 6.3.b of this rule.

6.2.d. All bags containing infectious medical waste shall be red in color except that infectious medical waste that is to be steam treated shall be contained in orange bags and marked with autoclave tape or other heat-activated ink which will indicate whether or not the appropriate temperature, as required by this rule, has been reached. Both red and orange bags shall be imprinted with the international biohazard symbol and the words "infectious medical waste" or "biomedical waste" or "biohazard" or "regulated medical waste" if treatment is to occur off-site. Waste contained in red bags shall be considered infectious medical waste and managed as infectious medical waste. Waste contained in orange bags shall be managed as infectious medical waste prior to steam treatment and as solid waste after steam treatment, but shall not be removed from the orange bags.

6.2.e. In addition to other packaging, all infectious medical waste which is to be transported off-site shall also be packaged in double-wall corrugated fiberboard boxes or equivalent rigid containers. The boxes or containers shall be leak-resistant or lined with a tear-resistant leak-proof plastic bag.

6.2.f. Reusable containers shall be leak-proof and vermin-proof, shall have tight-fitting covers, and shall be kept clean and in good repair. Reusable containers shall be thor-

oroughly washed and disinfected if they are contaminated by or come in contact with improperly contained medical waste items, unless the surfaces of the containers have been protected from contamination by disposable liners, bags or other devices. Such disposable liners, bags or other devices shall be removed and handled as infectious medical waste. Red or orange bags may not be enclosed in bags of different colors.

6.2.g. Disinfection of the container shall be accomplished by one of the following methods:

6.2.g.1. Immersion in hot water at a temperature of at least one hundred and eighty degrees Fahrenheit (180° F) for a minimum of thirty (30) seconds;

6.2.g.2. Exposure to a chemical sanitizer by immersion in one of the following for a minimum of thirty (30) seconds: hypochlorite solution of one hundred parts per million (100 ppm) available chlorine; iodoform solution of twenty-five parts per million (25 ppm) available iodine; or quaternary ammonium solution of two hundred parts per million (200 ppm) active agent; or

6.2.g.3. Swabbing or rinsing the container with a chemical sanitizer double the strength specified in Section 6.2.g.2 of this rule or a chemical with equivalent sanitizing capabilities.

6.2.h. Employers shall make reasonable efforts to direct employees packaging infectious medical waste to use personnel protection equipment and shall provide training in its use.

6.3. Labeling Requirements.

6.3.a. Infectious medical waste to be transported off-site shall be labeled prior to being stored on-site or transported off-site. The label shall be securely attached to the outer layer of packaging and shall be clearly legible. The label may be a tag securely affixed to the package. Indelible ink shall be used to complete the information on the label, and the label shall be at least three (3) inches by five (5) inches in size. The following information shall be included on the label:

6.3.a.1. The name, address and business telephone ~~number~~ and fax numbers of the generator;

6.3.a. The words "infectious medical waste" or "biomedical waste" or "biohazard" or "regulated medical waste";

6.3.a.3. The name, address and business telephone ~~number~~ and fax numbers of all transporters, treatment facilities, or other persons to whose control the infectious medical waste is being transferred and the permit numbers of transporters, if applicable; and

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6.3.a.4. The date on which the infectious medical waste was packaged.

6.3.b. Recognizable treated noninfectious medical waste shall be labeled prior to being transported off-site. Treated medical waste that will pass through a screen with a one-half inch ($\frac{1}{2}$ ") grid shall be considered not recognizable. The label shall be sized and attached in the manner required by Section 6.3.a of this rule for infectious medical waste. The following information shall be included on the label:

6.3.b.1. The name, address and business telephone ~~number~~ and fax numbers of the generator;

6.3.b.2. The name, address, and business telephone ~~number~~ and fax numbers of the facility at which the waste was rendered noninfectious;

6.3.b.3. The weight of the treated noninfectious medical waste and the method of treatment;

6.3.b.4. A signed and dated certification by the facility at which the waste was rendered noninfectious which states: "I hereby certify under penalty of law that this waste has been rendered noninfectious in accordance with procedures required by Infectious Medical Waste, 64 CSR 56."

§64-56-7. Management of Spills of Infectious Medical Waste.

7.1. All infectious medical waste management facilities shall keep a spill containment and cleanup kit within the vicinity of any area where infectious medical waste is managed on a bulk storage basis. The location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting infectious medical waste shall carry a spill containment and cleanup kit in the vehicle whenever infectious medical waste is conveyed.

7.1.a. The kit shall contain an amount of absorbent material sufficient to have a rated capacity of one (1) gallon of liquid for every cubic foot of infectious medical waste that is normally managed in the area for which the kit is provided or of ten (10) gallons, whichever is less.

7.1.b. The kit shall contain one (1) gallon of hospital grade disinfectant in a sprayer capable of dispersing its charge in a mist or in a stream at a distance. The disinfectant shall be hospital-grade and effective against myco bacteria.

7.1.c. The kit shall contain enough red plastic bags to enclose one hundred and fifty percent (150%) of the maximum quantity stored or transported. The bags shall meet the American Society for Testing and Materials drop weight test (ASTM-D-959-80) using one hundred twenty-five (125) pounds or shall be three (3) mils thick or the equivalent and shall be accompanied by sealing tape or devices and labels or tags. These bags shall be large enough to

enclose any box or other container normally used for infectious medical waste management by that facility or carried by a transport vehicle.

7.1.d. The kit shall contain two (2) new sets of overalls, gloves, boots, caps, and devices to protect the eyes and respiratory tract, and tape for sealing wrists and ankles. The overalls, boots and caps shall be oversized or fitted to the infectious medical waste workers or transporters, and shall be made of materials impermeable to liquids. Boots may be of thick rubber and gloves shall be of heavy neoprene or equivalent material. Boots, gloves and breathing devices may be reused if disinfected between uses.

7.1.e. The kit shall contain an adequate first aid kit and one hundred (100) yards of boundary marking tape.

7.2. Immediately following a spill of infectious medical waste or its discovery, all individuals present shall leave the area until any aerosol settles.

7.3. The cleanup crew shall implement the following procedures for cleaning up a spill:

7.3.a. Put on cleanup outfits as described in Section 7.1.4 of this rule and secure the spill area from entry by unauthorized persons;

7.3.b. Spray all broken containers of infectious medical waste with disinfectant;

7.3.c. Place broken containers and spillage in the packing bags in the kit;

7.3.d. Disinfect and take other steps necessary to clean up the area;

7.3.e. Clean and disinfect non-disposable items and clothing;

7.3.f. Remove cleanup outfits and place disposable items in a cleanup bag; and

7.3.g. Take prompt steps to initiate procedures for the replenishment of the containment and cleanup kit.

7.4. When a spill involves a single container of infectious medical waste with a weight of less than fifty (50) lbs. and a volume of spilled liquid of less than one (1) quart, the individual responsible for the cleanup may elect to use dress and procedures other than those required by Section 7.1.d of this rule. Any proposed alternate procedures for small quantity spills shall be specified in the infectious medical waste management plan and shall provide protection to the health of workers and the public equivalent to that provided by the procedures specified in Section 7.2 of this rule.

§64-56-8. Storage of Infectious Medical Waste.

8.1. This section is applicable to the storage of infectious medical waste at any time after packaging (sealing) for transport, including time spent during transportation and at all treatment and disposal sites or facilities.

8.2. Infectious medical waste other than sharps shall not be stored for more than thirty (30) days prior to transportation to an infectious medical waste management facility, even if refrigerated: Provided, that the total amount of storage time, including transportation to an infectious medical waste management facility, shall not exceed forty-five (45) days. Facilities that treat infectious medical waste on-site shall not store the infectious medical waste more than thirty (30) days.

8.3. Infectious medical waste shall be stored in a specifically designated area located at or near the treatment site, or at the pickup point if it is to be transported off-site for treatment.

8.4. The manner of storage shall maintain the integrity of the containers; prevent the leakage of waste from the container; provide protection from water, rain and wind, and maintain the waste in a non-putrescent state.

8.5. All storage areas shall be constructed of materials which are durable, easily cleanable, impermeable to liquids, and vermin-proof.

8.6. Carpets and floor coverings with open seams in which water may be entrapped shall not be used in storage areas. All floor drains shall discharge directly to a sanitary sewage disposal system which is in compliance with Sewage System Rules, 64 CSR 9 or other containment system which prevents any spilled materials from reaching the environment.

8.7. All storage areas shall be kept clean and in good repair.

8.8. All storage areas shall have access control that limits access to those persons specifically designated to manage infectious medical waste. The areas shall be posted prominently with the international biohazard symbol and with warning signs located adjacent to the exterior of entry doors, gates or lids which indicate the use of the area for storage of infectious medical waste and that entry to unauthorized persons is denied.

8.9. Infectious medical waste shall not be placed in chutes at any time.

8.10. Compaction of infectious medical waste or subjecting infectious medical waste to violent mechanical action is prohibited unless as a part of a specific treatment process approved by the secretary.

§64-56-9. Transportation.

9.1. This section applies to all transportation of infectious medical waste over roads or highways within West Virginia, regardless of point of origin or intended disposal, except as

specified in Sections 9.2 and 9.3 of this rule.

9.2. A small quantity generator may transport his or her infectious medical waste to a permitted infectious medical waste management facility, or may arrange for transport by his or her employee as follows:

9.2.a. An employee who transports the infectious medical waste shall be trained in the proper handling of infectious medical waste as required by this rule; and

9.2.b. The infectious medical waste shall be delivered within forty-five (45) days of its generation, or

9.2.c. Via the U.S. postal service, if the requirements set by that agency are met.

9.3. A generator that transfers infectious medical waste on-site shall be exempt from Sections 9.9, 9.10, 9.11 and 9.12 of this rule: Provided, That:

9.3.a. On-site transfer of infectious medical waste is covered in the infectious medical waste management plan; and

9.3.b. No off-site infectious medical waste is knowingly and routinely accepted for on-site transfer.

9.4. No person shall knowingly receive for transportation any infectious medical waste that is not packaged and labeled in accordance with Section 6 of this rule.

9.5. A transporter shall deliver infectious medical waste in West Virginia only to a permitted infectious medical waste management facility. Transporters of infectious medical waste out of state shall transport it to a facility permitted by the receiving jurisdiction.

9.6. All vehicles transporting infectious medical waste shall be prominently identified while transporting the infectious medical waste with the following, except for vehicles used as specified in Sections 9.2 and 9.3 of this rule:

9.6.a. The international biohazard symbol;

9.6.b. The words "infectious medical waste", or "biomedical waste", or "biohazard" or "regulated medical waste";

9.6.c. The number of the transporter's permit issued by the secretary; and

9.6.d. If applicable, a placard in accordance with United States Department of Transportation requirements. Removable signs are acceptable.

9.7. Vehicles that transport infectious medical waste:

9.7.a. Shall include a cargo-carrying portion that shall be closed and secured except when loading or unloading infectious medical waste to prevent unauthorized access and exposure to wind and precipitation;

9.7.b. Shall be designed and constructed so as to contain any spillage;

9.7.c. Shall be cleaned and disinfected following leakage or spills as provided in Section 6.2.g.3 of this rule;

9.7.d. Shall be cleaned and disinfected prior to using the conveyance for any other purpose as provided in Section 6.2.g.3 of this rule; and

9.7.e. Shall not be used to transport food, foodstuffs, food additives, food containers or any substances to be ingested by people or animals or applied to food or feed simultaneously with the transport of infectious medical waste.

9.7.f. Separate, removable cargo-carrying containers are acceptable and if used, Sections 9.7.a through 9.7.e of this rule shall apply to the containers in lieu of the entire vehicle.

9.8. All vehicles transporting infectious medical waste shall carry a spill containment and cleanup kit as required by Section 7 of this rule in the vehicle whenever infectious medical waste is conveyed. Spills of infectious medical waste during transportation shall be managed as required by Sections 7.2 and 7.3 of this rule. Any spill of fifty (50) pounds or more shall be reported as soon as possible to the employer and the secretary. Direct physical contact of the transport vehicle or equipment with infectious medical waste shall be considered and managed as a spill.

9.9. No person shall transport infectious medical waste in West Virginia for another who does not possess a permit issued by the secretary, and, if applicable, valid authority issued by the public service commission. Permits issued by the secretary shall not be transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation.

9.10. An application for a permit to transport infectious medical waste shall be made in writing to the secretary on a form prescribed by the secretary. The application form shall be signed by the applicant or his or her authorized representative. The application shall contain at a minimum the following:

9.10.a. The applicant's name;

9.10.b. The business address and telephone ~~number~~ number and fax numbers of the applicant, including both headquarters and local office;

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9.10.c. The make, model and license number of each vehicle to be used to transport infectious medical waste within West Virginia;

9.10.d. The counties and cities in West Virginia in which the transporter will operate;

9.10.e. The name of any person or firm other than reported in Section 9.10.1 of this rule that is associated with the applicant or any other name under which that person or firm does business;

9.10.f. The name of any other person or firm using any of the same vehicles and operators;

9.10.g. The name and telephone ~~number~~ number and fax numbers of a person who may be contacted in the event of an accident or spill;

9.10.h. Verification that the applicant has established a program of and is providing training for employees involved in the transportation of infectious medical waste as required by this rule; and

9.10.i. Designation of the treatment facilities to be used.

9.11. The application shall be accompanied by a fee per transport vehicle according to the fee schedule shown in Table 64-56A found at the end of this rule. An application for renewal shall be submitted with the fee forty-five (45) days prior to the expiration date of an existing permit.

9.12. Once the application has been approved by the secretary, and upon verification that the applicant has been duly authorized by the public service commission, if applicable, a permit shall be issued to the applicant. All transport vehicles shall display the decal provided by the public service commission as required by the commission.

9.13. Upon request, the transporter shall provide the secretary with information needed for the investigation of the handling of particular infectious medical waste including, but not limited to, the names, addresses and telephone and fax numbers of transporters from or to whom the transporter has received or transferred infectious medical waste and infectious medical waste management facilities and generators with which the transporter has a contract or agreement for services.

9.14. All infectious medical waste transport vehicles shall be subject to inspection by the secretary without prior notice to evaluate compliance with this rule.

§64-56-10. Methods of Treatment.

10.1. General.

10.1.a. All infectious medical waste shall be treated by one of the following methods:

10.1.a.1. Incineration as described in Section 10.2 of this rule;

10.1.a.2. Steam treatment as described in Section 10.3 of this rule;

10.1.a.3. Discharge to a sanitary sewer as described in Section 10.4 of this rule;

or

10.1.a.4. Any other alternative method approved in writing and permitted by the secretary according to the provisions of Section 10.5 of this rule.

10.1.b. The residue or ash remaining after the treatment of infectious medical waste in accordance with this rule becomes noninfectious medical waste and may be disposed of in the same manner as ash from solid waste incineration and as provided in subdivision 10.2.5 of this rule.

10.2. Incineration.

10.2.a. All owners and operators of infectious medical waste incinerators are required to comply with applicable State laws and with rules of the West Virginia Air Pollution Control Commission.

10.2.b. Whenever infectious medical waste is introduced into an incinerator, all the waste shall be subjected to a burn temperature of not less than one thousand four hundred degrees Fahrenheit (1400° F) for a period not less than one (1) hour. Gases generated by the combustion shall be subjected to a temperature of not less than one thousand eight hundred degrees Fahrenheit (1800° F) for a period of one (1) second or more.

10.2.c. An incinerator used for treatment of infectious medical waste shall have interlocks or other process control devices to prevent feeding of the incinerator until the conditions specified in Section 10.2.b of this rule can be achieved. In the event low temperatures occur, facilities shall have automatic auxiliary burners which are capable, excluding the heat content of the waste, of independently maintaining the secondary chamber temperature at the minimum of one thousand eight hundred degrees Fahrenheit (1800° F).

10.2.d. There shall be continuous monitoring and recording of primary and secondary chamber temperatures. Monitoring data shall be maintained for a period of three (3) years.

10.2.e. All combustible waste shall be converted by the incineration process into ash that is not recognizably in its pre-incineration form. Incinerator ash shall be tested at least quarterly, using a commingled random sample, for total organic carbon content, and annually for lead, mercury, cadmium, and other heavy metals. A maximum of five percent (5%) fixed carbon shall be permitted (minimum ninety-five percent (95%) burnout).

10.2.f. Two (2) years following the effective date of this rule, all individuals who operate infectious medical waste incinerators shall be registered with the secretary. The secretary shall issue a registration number to individuals who complete a course of study approved by the secretary; obtain a passing score on a written examination; and pay the fee shown in Table 64-56A found at the end of this rule.

10.2.g. Facilities with incinerators in operation at the time this rule becomes effective may apply to the secretary for a waiver to Sections 10.2.b through 10.2.d of this rule. The waiver, if granted, shall be in effect for a maximum of two (2) years after issuance of applicable final Environmental Protection Agency rules relating to medical waste incineration and shall be contingent upon submission of plans to upgrade the facility so as to be in full compliance with Sections 10.2.b through 10.2.d of this rule. The plans shall be submitted as part of the infectious medical waste facility management plan required in Section 5 of this rule and shall be subject to approval by the secretary.

10.3. Steam Treatment.

10.3.a. A steam treatment process for infectious medical waste shall at all times maintain:

10.3.a.1. A temperature of not less than two hundred and fifty degrees Fahrenheit (250° F) for ninety (90) minutes at fifteen (15) pounds per square inch of gauge pressure; or

10.3.a.2. A temperature of two hundred and seventy-two degrees Fahrenheit (272° F) for forty-five (45) minutes at twenty-seven (27) pounds per square inch; or

10.3.a.3. A temperature of two hundred and fifty degrees Fahrenheit (250° F) for twenty-eight (28) minutes at eighty (80) pounds per square inch; or

10.3.a.4. A temperature of two hundred and seventy degrees Fahrenheit (270° F) for sixteen (16) minutes at eighty (80) pounds per square inch; or

10.3.a.5. A temperature of two hundred and seventy degrees Fahrenheit (270° F) for thirty (30) minutes at thirty-two (32) pounds per square inch; or

10.3.a.6. Other combinations of operational temperatures, pressure and time approved by the secretary. Other combinations may be approved if the installed equipment has been proved to achieve a reliable kill of all infectious microorganisms in infectious medical waste at design capacity. Complete and thorough testing of such other combinations of temperature and pressure shall be fully documented, including tests of the capacity to kill *Bacillus stearothermophilus*. Longer steam treatment times are required when a load contains a large quantity of liquid.

10.3.b. Each package of infectious medical waste to be treated with steam shall have

a tape attached that will indicate if the steam treatment temperature has been reached. The infectious medical waste shall not be considered satisfactorily treated if the indicator does not indicate that the treatment temperature was reached during the process. Each package shall also be labeled according to the requirements of Section 6.3.b of this rule after treatment if recognizable.

10.3.c. Steam treatment units shall be evaluated under full loading for effectiveness with spores of *Bacillus stearothermophilus* no less than once per every forty (40) hours of operation.

10.3.d. A log shall be kept at each steam treatment unit that is complete for the preceding three (3) year period. The log shall record:

10.3.d.1. The date, time and operator of each usage;

10.3.d.2. The type and approximate amount of waste treated;

10.3.d.3. The post-treatment reading of the temperature sensitive tape;

10.3.d.4. The dates and results of calibration; and

10.3.d.5. The results of the testing required by Section 10.3.3 of this rule.

Where multiple steam treatment units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location. The consolidated logs shall be retained for three (3) years and be available for review.

10.4. Sanitary Sewer.

Liquid infectious medical waste may be discharged to a sanitary sewer through a drainage fixture of a size and type adequate to discharge the waste in a sanitary manner to a sewer system approved by the department according to Sewage System Rules, 64 CSR 9. The use of a grinder to reduce infectious solid matter to a size or consistency which can be discharged to a sewer is prohibited.

10.5. Alternative Methods.

10.5.a. The secretary may approve an alternative method of treatment not described in this rule if the secretary determines that the proposed process will render infectious medical waste noninfectious and will provide protection to the health and safety of the public and workers at least the equivalent to the methods found at Sections 10.2, 10.3 or 10.4 of this rule.

10.5.b. The secretary may issue provisional approval to any alternate method until an appropriate trial period can validate performance. Alternate methods employing disinfection must have the disinfectant registered for that purpose in accordance with the federal Insecticide,

Fungicide, and Rodenticide Act as amended. If the process fails to provide adequate treatment when operated according to manufacturer's instructions, the provisional approval shall be revoked.

10.5.c. In addition to complying with other sections of this rule, an application for approval of an alternate method shall include:

10.5.c.1. A listing of the classes and amounts of infectious medical waste the method could be employed to treat;

10.5.c.2. A copy of the detailed plans for the device used in the method;

10.5.c.3. A written summary of the proper operation of the method and device;

10.5.c.4. A copy of the operation and maintenance manual for the process or device;

10.5.c.5. Copies of approval and denial letters from other states where the process has been evaluated; and

10.5.c.6. A copy of an evaluation report provided by a testing laboratory independent of the applicant using a testing protocol approved by the secretary confirming the efficacy of the treatment process and that the process does not produce a hazardous waste, discharge or air emission.

10.5.c.7 To evaluate alternative treatment technologies, the secretary shall use the procedures outlined in the following referenced manual that is incorporated in this rule: State and Territorial Association on Alternate Treatment Technologies, Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies (April 1994).

10.5.c.8 A non refundable alternative technology evaluation fee shall be submitted with the application in accordance with Table 64-56A at the end of this rule.

§64-56-11. Commercial Infectious Medical Waste Management Facilities.

11.1. This section of this rule applies only to commercial infectious medical waste management facilities.

11.2. A commercial infectious medical waste management facility may not utilize incineration technology in any form, including the manufacture or burning of refuse-derived fuel in any form.

11.3. A commercial infectious medical waste management facility shall have effective controls for the management of infectious medical waste to ensure the protection of public

health, safety, welfare and the environment.

11.4. The secretary shall conduct an investigation of the infectious medical waste stream in the region affected by the proposed facility and determine that programs have been established to minimize and reduce the infectious medical waste stream the facility will serve prior to issuing a permit. The secretary may issue a permit only if he or she makes a specific finding that as to the medical waste stream the proposed facility will be consistent with the legislative findings and purpose stated in W. Va. Code §20-5J-2.

11.5. No person may establish, construct, operate, maintain, or allow the use of property for a commercial infectious medical waste management facility within: ~~an area where the secretary has determined, after consultation with relevant State and federal agencies, that the facility will be in violation of applicable State or federal laws or regulations concerning;~~

11.5.a. ~~Wetlands~~ The one-hundred (100) year flood plain;

11.5.b. ~~Any endangered or threatened species of animal or plant;~~ Five hundred (500) feet of a dwelling, measured from the edge of the boundary of the facility, unless written permission is received from the owner of the dwelling;

11.5.c. ~~Surface water;~~ An area where the secretary has determined, after consultation with relevant state and federal agencies, that the facility will be in violation of applicable state or federal laws or regulations concerning;

11.5.c.1. Wetlands;

11.5.c.2. Any endangered or threatened species of animal or plant;

11.5.c.3. Surface water;

11.5.c.4. Groundwater quality; or

11.5.c.5. The emission of any air contaminant.

11.6. A proposed infectious medical waste management facility shall provide evidence of financial capability suitable to the scope of the facility to the secretary.

~~11.7. To obtain a permit to own, operate and construct a commercial infectious medical waste management facility, a person shall announce the public hearing required by subsection 11.9 of this rule by publishing a Class II legal advertisement in a qualified newspaper as defined in W. Va. Code, §59-3-1 which serves the county in which the proposed facility is to be located. The advertisement shall include:~~

11.7. No person may own, construct, modify or operate a commercial infectious medical

waste facility, nor may any person store, transport, treat or dispose of any infectious medical waste without first obtaining a permit from the secretary.

11.8. The owner of an infectious medical waste facility is responsible for insuring that the facility has a permit.

11.9. In order to obtain approval to locate a commercial infectious medical waste facility, not under permit to operate as of April 12, 1997, an applicant shall:

11.9.a. File a pre-siting notice with the secretary, the division of environmental protection and the county commission or commissions and the local solid waste authority or authorities of the county or counties in which the facility is to be located. Such notice shall be available for public review, and shall include:

11.9.a.1. A description of the location at which the proposed facility may be sited;

11.9.a.2. Information concerning the anticipated size of the proposed facility;~~and~~

11.9.a.3. An estimate of the volume, type, and origin of the infectious medical waste to be handled at the proposed facility;

11.9.a.4. A United States Geological Survey (USGS) topographic map showing the location and anticipated boundaries of each site being considered for the proposed facility;

11.9.a.5. A description of the technology that is to be used in the treatment of infectious medical waste;

11.9.a.6. The name, address and telephone and fax numbers of the owner or applicant of the proposed facility;

11.9.a.7. The name, address and telephone and fax numbers of the operator of the proposed facility, if different from the owner or applicant; and

11.9.a.8. Other information that the secretary may require.

~~11.7.1.4. The announcement of the date, time and place where the hearing is to be conducted, shall be made at least fourteen (14) but not more than forty-five (45) days prior to the hearing.~~

11.9.b. In accordance with W. Va. Code §20-5K-3, when the pre-siting notice required by this section is filed, the county commission shall publish a Class II legal advertisement, in compliance with the provisions of W. Va. Code Chapter 59, Article 3, in a newspaper of general circulation in the counties wherein the commercial infectious medical waste facility is to be

located.

11.9.b.1. The Class II legal advertisement shall be published within ten (10) days of receipt of the pre-siting notice, and shall include:

11.9.b.1.A. The same information concerning the proposed facility that is in the pre-siting notice;

11.9.b.1.B. Notice to the public that a county-wide referendum determining the siting of the proposed facility can be held upon an affirmative vote of the majority of the county commissioners; or upon the written petition of registered voters residing in the county equal to not less than fifteen percent (15%) of the number of votes cast within the county for governor at the preceding gubernatorial election, which petition shall be filed with the county commission within sixty (60) days after the last date of publication of the Class II advertisement provided in this section.

11.10. In accordance with W. Va. Code §20-5K-3, upon an affirmative vote of the majority of the county commissioners or upon the written petition of registered voters residing in the county equal to not less than fifteen percent (15%) of the number of votes cast within the county for governor at the preceding gubernatorial election, which petition shall be filed with the county commission within sixty (60) days after the last date of publication of the notice provided in this section, the county commission shall, upon verification of the required number of signatures on the petition, and not less than fifty-six (56) days before the election, order a referendum to be placed on the ballot.

11.10.a. The secretary of state shall prescribe the form of the petition which shall include the printed name, address and date of birth of each person whose signature appears on the petition.

11.10.b. Any referendum conducted pursuant to this section shall be held at the next primary, general or other county-wide election.

11.10.c. Such referendum is to determine whether it is the will of the voters of the county that a commercial infectious medical waste facility be located in the county.

11.10.d. Any election at which such question of locating a commercial infectious medical waste facility is voted upon shall be held at the voting precincts established for holding primary or general elections. All of the provisions of the general election laws, when not in conflict with the provisions of this article, apply to voting and elections hereunder, insofar as practicable.

11.10.e. The ballot, or the ballot labels where voting machines are used, shall have printed thereon substantially the following depending upon the type of facility to be located within the county:

Shall a commercial infectious medical waste management facility be located within
xxxxxxx County.

[] For the facility

[] Against the facility

(Place a cross mark in the square opposite your choice.)

11.10.e.1. If a majority of the legal votes cast upon the question is against the facility, then the county commission shall notify the local solid waste authority, the division of environmental protection, and the secretary of the department of health and human resources of the result and the commercial infectious medical waste facility may not proceed any further with the application.

11.10.e.2. If the majority of the legal votes cast is against the question, the question may be submitted to a vote at any subsequent election in the manner herein specified: *Provided*, That the question may not be resubmitted to a vote until two years after the date of the previous referendum.

11.11. If a majority of the legal votes cast upon the question is for the facility, then the application process may proceed: *Provided*, that such vote is not binding on nor does it require the secretary to issue the permit.

~~11.8. A pre-siting notice shall be filed with the secretary and the applicable county solid waste authority within five (5) days of the publication of the legal advertisement required under Section 11.7 of this rule. The pre-siting notice shall include a certification of publication of the legal advertisement required under Section 11.7 of this rule from the newspaper in which the advertisement was published with a copy of the advertisement.~~

11.12. Permit Application Requirements. An application for a permit shall be submitted to the secretary in duplicate on forms prescribed by the secretary, and unless otherwise specified in this rule, shall include the following:

11.12.a. The name, mailing address, and location of the facility for which the application is submitted;

11.12.b. The name, address and telephone and fax numbers of the owner of the facility, and if the owner is an individual or a partnership, the social security number or numbers of the owner or partners;

11.12.c. The name, address and telephone and fax numbers of the manager of the facility, if different from the owner; and if the manager is an individual or partnership different from the owner, the social security number or numbers of the individual or partners;

11.12.d. A proposed infectious medical waste management plan as required by Section 5 of this rule. The infectious medical waste management plan shall be incorporated into the permit as part of the permit conditions;

11.12.e. A description of the legal documents upon which the applicant bases his or her legal right to enter and conduct operations on the facility permit area and whether that right is the subject of pending court litigation;

11.12.f. All application documents related to engineering and design plans and specifications as compiled, signed, and sealed by a professional engineer who is registered to practice in West Virginia;

11.12.g. Appropriate legible exhibits, including maps, figures, photographs, and tables, of appropriate scale to show all required details necessary to clarify information or conclusions;

~~11.9. A person proposing to own, construct and operate a commercial infectious medical waste management facility shall conduct a public hearing in the county where the proposed facility is to be located in accordance with the following guidelines:~~

~~11.9.1. A transcript of the hearing shall be available to the public and shall be submitted to the secretary.~~

~~11.9.2. Any person may submit oral or written statements and data concerning the proposed facility. Reasonable limits may be set on the time allowed for oral statements, and the written statements shall be submitted no later than ten (10) days after the close of public hearings.~~

~~11.10. If any data, information or arguments submitted during the public comment period raise substantial new questions concerning the proposed facility, the secretary shall:~~

~~11.10.1. Reopen or extend the public comment period to give interested persons an opportunity to comment on the information or argument submitted; or~~

~~11.10.2. Require an additional public hearing.~~

~~11.11. The applicant for a permit for a commercial infectious medical waste management facility shall maintain a public participation file. This file shall contain all the written comments received during the public comment period, copies of transcripts of all meetings held by the applicant and a copy of the applicant's written response to all written comment letters received during the written response period. This file shall be submitted to the secretary by the applicant as a part of the application package.~~

11.12.h. ~~The applicant shall arrange~~ Documentation of arrangements for a permitted facility facilities to receive all treated waste and wastewater;

11.12.i. ~~A commercial infectious medical waste management facility shall employ A treatment technology approved according to plan in accordance with the provisions of Section 10.3 through 10.5 of this rule;~~

11.12.j. ~~The applicant shall provide~~ Financial assurance in the form of a collateral bond, an escrow account or a letter of credit equal to the proposed cost of the project.

11.12.k. A proposed design and a general discussion of the proposed operating procedures;

11.12.l. A notarized signature of the owner or principal officer verifying that the information contained in the application is true and correct to the best of that individual's knowledge and belief;

11.12.m. A review of land use zoning in the area with particular attention given to areas where zoning variances will be required, where agricultural impact statements may be required, or where flood plain, river corridors, or wetlands are designated;

11.12.n. A description of the present land use within two (2) miles of the permit area. The discussion shall include, but not be limited to:

11.12.n.1. Impacts upon transportation facilities;

11.12.n.2. Impacts upon public and private water supplies;

11.12.n.3. Impact upon land use patterns;

11.12.n.4. Impacts upon agricultural, commercial and residential real estate values;

11.12.n.5. Impacts upon wildlife;

11.12.n.6. Impacts upon endangered or threatened species of animals or plants;

11.12.n.7. Impacts upon aesthetics;

11.12.n.8. Impacts upon socioeconomic conditions;

11.12.n.9. Impacts to water resources;

11.12.n.10. Impacts on sewage collection and treatment systems;

11.12.n.11. Impacts on local emergency response crews and firefighters;

11.12.n.12. Impacts upon known recreational, historical, archaeological, or environmentally unique areas; and

11.12.n.13. Other impacts as determined by the secretary.

11.12.o. A large-scale map with a minimum scale of one (1) inch equal to two hundred (200) feet and a maximum contour interval of ten (10) feet, or a 7.5 minute topographic map, showing the location of all of the following that occur either within the site boundaries or within two thousand five hundred (2,500) feet of the site;

11.12.o.1. Water supply wells;

11.12.o.2. Springs;

11.12.o.3. Wetlands (e.g., swamps, bogs, marshes);

11.12.o.4. Streams and drainages;

11.12.o.5. Public water supplies;

11.12.o.6. Other bodies of water;

11.12.o.7. Underground or surface mines;

11.12.o.8. Water quality monitoring points;

11.12.o.9. Occupied dwellings;

11.12.o.10. Roads;

11.12.o.11. Public buildings;

11.12.o.12. Sinkholes;

11.12.o.13. Property boundaries, including site property;

11.12.o.14. Current owners of record both surface and subsurface;

11.12.o.15. Easements or rights-of-way; and

11.12.o.16. One hundred (100) year flood plain boundary;

11.12.p. A description of present and proposed transportation routes and access roads, including any weight restrictions;

11.12.q. A description of buildings, treatment units, roads, and other structures to be constructed in conjunction with the facility, including the size of the construction and the number of miles of road to be constructed;

11.12.r. A description of emissions and discharges, such as dust, odors, gases, leachate, surface water runoff and collected groundwater, associated with facility preparation, construction, operation, closure and the time following closure of the facility; and

11.12.s. A non-refundable application fee according to the schedule shown in Table 64-56A at the end of this rule.

11.13. Modifications.

11.13.a. When a permit is modified, only the conditions subject to modification are reopened. All other conditions of the permit remain in effect for the duration of the permit.

11.13.b. The secretary may require additional information and, in the case of a major modification, may require submission of a new permit application.

11.13.c. Minor Modifications.

11.13.c.1. Modifications, except for major modifications as listed in this section, in the infectious medical waste plan may be made without notifying the secretary and shall be included in the next application for permit renewal.

11.13.c.2. Permits may be modified by the secretary at any time except for major modifications as listed in this section. Minor modification does not require the completion of the public notice procedures.

11.13.d. Major Modifications. A permittee shall submit an application for approval of a major modification before implementing the change. All major modifications shall be approved prior to implementation and require the opportunity for a public hearing as required by this rule unless an emergency is declared by the secretary. For the purpose of this section a major modification means:

11.13.d.1. The capacity of the commercial infectious medical waste facility will be increased over the permitted capacity by more than ten percent (10%);

11.13.d.2. The performance or operation of the surface water control system will be significantly affected;

11.13.d.3. A decrease in the quality or quantity of data from any environmental monitoring system will occur;

11.13.d.4. The amount or type of financial assurance will change;

11.13.d.5. The facility boundary will be significantly changed;

11.13.d.6. Authorization is being sought to construct an additional structure;

11.13.d.7. Different permitted facilities are being considered to receive treated waste or wastewater; or

11.13.d.8. Installing a new unit for the treatment of infectious medical waste or replacing existing treatment units not to include repair or improvements to existing units;

11.13.d.9 Changing the location of treatment;

11.13.d.10 Any other action that the secretary determines may present substantial endangerment to public health, safety or the environment; and

11.13.d.11. Other similar modifications as determined by the secretary.

11.13.d.12. Major modifications to an initial application for a new commercial infectious medical waste facility require the applicant to undergo a new pre-siting process as described in Sections 11.9. through 11.12 of this rule.

11.13.d.13. Permit renewals that contain major modifications shall be treated as major modifications.

11.14. Permit Suspension or Revocation.

11.14.a. Suspension. A commercial infectious medical waste facility permit may be suspended by order of the secretary for any of the following reasons:

11.14.a.1. Violation of, or failure to adhere to, W. Va. Code Chapter 20, Article 5J, this rule, the terms and conditions of the permit, or any order of the secretary issued thereunder;

11.14.a.2. Interference with a representative of the secretary in the performance of his or her duties; or

11.14.a.3. Discovery of failure in the application or during the permit issuance process to fully disclose all significant facts or the permittee's misrepresentation of any significant fact at any time.

11.14.b. Revocation. A commercial infectious medical waste facility permit may be revoked by order of the secretary for any of the following reasons:

11.14.b.1. An attempt by an applicant or permittee to obtain or renew a permit by means of fraud, deceit or material misrepresentation;

11.14.b.2. Any deficiency at the facility constituting an imminent pollution, health, or safety hazard;

11.14.b.3. Persistent violation of W.Va. Code Chapter 20, Article 5J, this rule, permit terms and conditions, or orders issued by the secretary under that Code Article or this rule;

11.14.b.4. Discovery of failure in the application, or during the permit issuance process, to fully disclose all significant facts or the permittee's misrepresentation of any significant fact at any time;

11.14.b.5. Failure to maintain proper bonding; if for any reason a permittee fails to maintain proper bonding, the secretary shall issue a cease and desist order and revoke the permit and the permittee shall become fully liable for the amount of the bond; or

11.14.b.6. Any cause which would require disqualification pursuant to this rule from receiving a permit upon original application.

11.14.c. Effect of Permit Suspension or Revocation.

11.14.c.1. Suspension. All infectious medical waste processing, treatment, storing or transfer activities and the receipt of any infectious medical waste at the facility shall cease immediately upon receipt of an order of suspension. Activities at the facility may recommence only after expiration of the order of suspension or upon revocation of that order by the issuing authority.

11.14.c.2. Revocation. All infectious medical waste processing, treatment, storing or transfer activities and the receipt of any infectious medical waste at the facility shall cease immediately upon receipt of an order of revocation. The facility owner shall submit either an application for a permit to close the facility or an application for a new commercial infectious medical waste facility permit within the time specified in the order of revocation.

11.14.c.3. Environmental Monitoring and Control. Environmental monitoring and control activities specified in an order of suspension or revocation shall continue at the commercial infectious medical waste facility for the duration of such order or until the authority that issued that order approves the cessation of such activities.

11.15. Transfer of Facility.

11.15.a. Permits issued by the secretary are not transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. An existing commercial facility that changes ownership may, however, continue to operate under the previous owner's permit conditions until such time as the secretary can process the new permit application required by this section, provided the new owner sends the secretary a letter in which the new owner:

11.15.a.1. Advises the secretary of such change of ownership including any management changes; and

11.15.a.2. Agrees to be bound by the conditions and policies established in the infectious medical waste management plan for that facility by the previous owner until such time as a new management plan can be approved by the secretary.

11.16. Application Review Within thirty (30) days of receipt of a permit application, compliance schedule, closure plan, or major modification application, the secretary shall determine whether such application, schedule, or plan is complete and shall notify the applicant of his or her determination in writing. If the secretary determines that such application, schedule, plan or modification is not complete, the notification shall advise the applicant of the deficiencies that require remedy.

11.16.a. The secretary may not begin the evaluation of a permit before receiving a complete application, including any supplemental information requested.

11.16.b. The secretary may not issue a permit before receiving a complete application.

11.16.c. The secretary shall request formal comments from the county commission of the county in which the facility is proposed to be located and from any municipal government within two (2) miles of the proposed location, with any negative response to such application from any commission or municipal government to be considered by the secretary and specific findings made as to the concerns raised by such responses.

11.17. Public Participation. When the secretary determines an application for a new facility to be complete, ~~A person proposing to own, construct and operate a commercial infectious medical waste management facility~~ he or she shall conduct a public hearing in the county where the proposed facility is to be located. ~~in accordance with the following guidelines:~~

11.17.a. When the secretary determines an application for a major modification to be complete, he or she shall instruct the applicant or permittee to give public notice. The secretary shall conduct a public hearing in the county where the proposed facility is to be located whenever he or she receives a request.

11.17.a.1. Public hearings shall be conducted in accordance with the following guidelines:

11.17.a.2. Public notice of a public hearing shall be given at least thirty (30) days before the hearing. Public comment will be accepted during those thirty (30) days.

11.17.a.3. Public notice shall be given by the following methods:

11.17.a.3.A. By mailing a copy of a notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such requests; and

11.17.a.3.B. By the applicant publishing the public notice as a Class II legal advertisement in a qualified newspaper, as defined in W. Va. Code §59-3-1, serving the county where the facility will be located. The secretary shall also require that legal advertisement be placed in newspapers of adjacent counties when a proposed facility is within two (2) miles of a county line. The cost of the publication will be the responsibility of the applicant who shall send a certification of publication to the secretary within twenty (20) days after publication; and

11.17.a.3.C. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

11.17.a.4. All public notices issued shall contain the following information:

11.17.a.4.A. The name and address of the office processing the permit action for which notice is being given;

11.17.a.4.B. The name and address of the permittee or permit applicant, and if different, of the facility or activity regulated by the permit;

11.17.a.4.C. A description of the activities covered in the application, including the type of commercial infectious medical waste facility, the types, amounts, and origins of infectious medical wastes to be handled, site improvements, and infectious medical waste handling methods;

11.17.a.4.D. The name, address and telephone and fax numbers of a person from whom interested persons may obtain further information, including copies of the application;

11.17.a.4.D.1. The availability of the application shall include, but not be limited to, copies placed at the courthouse of the county in which the facility is to be located, the city or town hall of any municipal government within two (2) miles of the proposed location of the facility and all public libraries in the county.

11.17.a.4.D.2. Copies of the application shall be available from the secretary at no cost.

11.17.a.4.E. A brief description of the comment procedures and the date, time and place of the hearing, and other procedures by which the public may participate in the final permit decision;

11.17.a.4.F. A general description of the location of proposed permit area including streams;

11.17.a.4.G. A clear and accurate location map. A map of a scale and detail found in the West Virginia official state highway map is the minimum standard for acceptance. The map size shall be at a minimum two (2) inches by two (2) inches. Longitude and latitude lines and a north arrow shall be indicated on the map, and such lines will cross at or near the center of the proposed permit area;

11.17.a.4.H. A reference to the date of previous public notices relating to the permit;

11.17.a.4.I. For major modifications, the public notice shall state:

11.17.a.4.I.1. That any interested person may submit written comment on the application, and that such comments shall include a concise statement of the nature of the issues raised;

11.17.a.4.I.2. That any interested person may request a public hearing, and that such request shall include a concise statement of the nature of the issues raised; and

11.17.a.4.I.3. That the secretary shall conduct a public hearing in the county where the proposed facility is to be located whenever he or she receives a request.

11.17.a.5. An official transcript of the hearing shall be available to the public from the secretary. ~~and shall be submitted to the secretary~~

11.17.a.6. Any person may submit oral or written statements and data concerning the proposed facility. Reasonable limits may be set on the time allowed for oral statements, and the written statements shall be submitted no later than ten (10) days after the close of public hearings.

11.17.a.7. If any data, information or arguments submitted during the public comment period raise substantial new questions concerning the proposed facility, the secretary shall:

11.17.a.7.A. Reopen or extend the public comment period to give

interested persons an opportunity to comment on the information or argument submitted; or

11.17.a.7.B. Require an additional public hearing.

11.17.a.8. The applicant for a permit for a commercial infectious medical waste management facility shall maintain a public participation file. This file shall contain all the written comments received during the public comment period, copies of minutes of all meetings held by the applicant and a copy of the applicant's written response to all written comment letters received during the written response period. This file shall be submitted to the secretary by the applicant ~~as a part of the application package~~ at the end of the comment period.

11.17.a.9. Based on comments received at the public hearing or upon written recommendations received, the secretary may within thirty (30) days after ~~receipt of the permit application~~ the close of the public comment period, require the person who submitted the application to furnish additional information regarding the impact the siting of the proposed facility may have upon wetlands, endangered or threatened species of plants and animals, surface waters, underground waters, air quality, and other matters as determined by the secretary comments received.

11.18. Permit Decision and Effective Date of Permit.

11.18.a. Within thirty (30) days of the close of the public comment period on an application for a new facility, or major modification of an existing permit, the secretary shall respond in writing to the comments received.

11.18.b. After comments have been responded to, the secretary shall issue a final permit decision. The secretary shall provide written notification of his or her decision to the applicant and to each person who has submitted written comments or requested notice of the final permit decision. For the purposes of this section, a "final permit decision" means the final decision of the secretary to grant, deny, revoke and reissue, or terminate a permit.

11.18.c. In the case of an application for a new facility, the secretary shall grant or deny the application as filed and as made available to the public pursuant to the provisions of this section. The secretary shall provide the reasons therefor in his or her written notification to the applicant. This notification shall also include reference to the procedures for appealing the final permit decision.

11.18.d. The secretary may refuse to grant a permit for any of the following reasons:

11.18.d.1. If an applicant or permittee has attempted to obtain or renew a permit by means of fraud, deceit or material misrepresentation;

11.18.d.2. Discovery of failure in the application or during the permit issuance process to fully disclose all significant facts or the permittee's misrepresentation of any signifi-

cant fact at any time:

11.18.d.3. The secretary determines, based on comments and recommendations received, that the facility is incompatible with existing or proposed land use patterns, including, but not limited to: transportation facilities; public water supplies; water resources; agricultural, commercial and residential real estate values; aesthetics; socioeconomic conditions generally; or if it endangers public health, safety or well being.

11.18.e. A final permit decision shall become effective not less than thirty (30) days after the date of notice of the decision, unless an earlier date is requested by the applicant and agreed upon by the secretary.

11.19. A retailer of sharps to be used by individuals in their own medical treatment may establish a small commercial infectious medical waste management facility to be used solely for the treatment of sharps sold by and returned to the retailer for treatment. Such small commercial infectious medical waste management facility shall apply for and obtain a permit according to the provisions of Section 4 of this rule. In addition to the requirements of Section 4, the application shall include a letter describing the location and estimated volume of sharps to be treated and a certified letter from an approved solid waste disposal facility agreeing to accept the treated wastes. Such small commercial infectious medical waste management facility shall comply with ~~Section Sections~~ 6 and 10 of this rule, and may be exempted by the secretary from the requirements of ~~Section 11.4 through 11.15~~ Sections 11.9 through 11.18 of this rule.

§64-56-12. Requirements Related to Manifests.

12.1. Except as specified in Section 12.9 of this rule, the generator of infectious medical waste that is to be transported off-site for storage or treatment shall initiate a four-part manifest which is available from or approved by the secretary. Copy three (3) of the manifest shall be retained by the generator after acceptance by the transporter. Copy two (2) of the manifest shall be retained by the transporter after acceptance by the treatment facility. Copy one (1) of the manifest shall be retained by the treatment facility: The treatment facility shall forward the original to the generator as required by Section 12.8 of this rule. A transporter who commingles loads shall initiate a new manifest as a generator. He or she shall submit the first copy of the original manifest back to the actual generator after receiving the first copy of the manifest for the commingled infectious medical waste from the treatment facility, along with a photocopy of the commingled load manifest.

12.2. If the generator does not receive the completed manifest from the treatment facility within fifty (50) days after the date the medical waste was accepted by the transporter, the generator shall report this fact to the secretary.

12.3. A transporter shall not accept infectious medical waste from a generator unless the waste is accompanied by a manifest with the generator portion completed, signed, and dated by the generator.

12.4. A transporter shall in the presence of the generator or, in the event of multiple transporters, in the presence of the previous transporter, complete the transporter portion of the manifest, including a handwritten acceptance signature and date of acceptance, and shall immediately give a signed copy of the manifest to the generator or previous transporter, with any discrepancies in manifest information noted on the manifest copy.

12.5. An infectious medical waste management facility shall not accept more than fifty (50) pounds of infectious medical waste from a generator per month or any quantity of infectious medical waste from a transporter unless it is accompanied by a properly completed manifest.

12.6. An infectious medical waste management facility shall, in the presence of the generator or transporter, complete the appropriate transport or storage, treatment or disposal facility portion of the manifest, including a handwritten acceptance signature and date of acceptance, and immediately give a signed copy of the manifest to the generator or transporter, with any discrepancies in manifest information noted on the manifest copy.

12.7. The infectious medical waste treatment facility shall record on the manifest the date on which the shipment was received and accepted by the facility.

12.8. The infectious medical waste treatment facility shall keep one (1) copy of the completed manifest as part of the facility operating record and shall forward the original to the generator within seven (7) days after treatment.

12.9. Small quantity generators who elect to transport their own infectious medical waste are not required to use a manifest.

12.10. In instances when an infectious medical waste management facility accepts less than fifty (50) pounds of infectious medical waste from a small quantity generator, the facility shall maintain a log of such receipts which includes, at a minimum, the following:

12.10.a. The name and address of the generator;

12.10.b. The weight of the waste received;

12.10.c. The date of receipt of the waste; and

12.10.d. The signature of the person receiving the waste.

12.11. Manifests and logs shall be retained by all parties for a period of not less than three (3) years. The period of retention of records is extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the secretary. These records shall be available for inspection by the secretary upon request.

12.12. Nothing in this rule shall prevent any hospital or other facility which receives

infectious medical waste from any small quantity generator, including any ambulance company, from requiring a completed manifest as more fully described in Sections 12.1 through 12.5 of this rule.

§64-56-13. Record Keeping and Reporting.

13.1. All pertinent records required by this rule shall be retained for a period of not less than three (3) years.

13.2. The period of retention established in Section 13.1 of this rule shall extend automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the secretary.

13.3. All records shall be made available for inspection and or duplication by the secretary or his or her duly authorized representative upon request.

13.4. All generators, except small quantity generators and those listed in Section 2 of this rule, commercial storage and transfer facilities and treatment facilities shall submit a report annually covering the preceding calendar year to the secretary in a format specified by the secretary by the twentieth day of January and additional reports at such times the secretary judges necessary setting out the quantity of waste generated during a particular time period and the disposition of the infectious medical waste. Transporters shall submit these reports on a quarterly basis.

§64-56-14. Inspections; Right of Entry; Sampling; Reports and Analyses; Subpoenas.

Inspections and other monitoring activities are required to be conducted according to the provisions of W. Va. Code §§~~20-5E-12~~ 22-18-13 and 20-5J-7 which are outlined in this section.

14.1. Upon the presentation of proper credentials and at reasonable times, the secretary has the authority to enter any building, property, premises, place, vehicle or permitted facility where infectious medical waste is or has been generated, handled, treated, stored, transported or disposed of for the purpose of promptly investigating any person's compliance with the provisions of relevant State law, this rule or permits issued under this rule.

14.2. The secretary is required to make periodic inspections of every permitted facility as necessary to effectively implement and enforce the requirements of relevant State law, this rule or permits issued in accordance with this rule. After an inspection is made, a report is to be prepared and filed with the secretary. A copy of the inspection report is required to be promptly furnished to the person in charge of the building, property, premises, place, vehicle or facility. All inspection reports are available to the public in accordance with the provisions of W.Va. Code §§29B-1-1 et seq.

14.3. Whenever the secretary has cause to believe that any person is in violation of any

provision of relevant State law, this rule, any condition of a permit issued by the secretary, or any order issued under this rule, he or she is required to immediately order an inspection of the building, property, premises, place, vehicle or permitted facility at which the alleged violation is occurring.

14.4. Upon presentation of proper credentials and at reasonable times, the secretary has the authority to enter any establishment, building, property, premises, vehicle or other place maintained by any person where infectious medical waste is being or has been generated, transported, stored, treated or disposed of to inspect and take samples of wastes and the contents of any containers or labeling for such wastes. A receipt describing such samples, and, if requested, a portion of such sample equal in volume or weight to the portion retained is to be given to the owner, operator or agent in charge prior to the sample being taken from the premises. The secretary is required to provide a copy of any analysis to the owner, operator or agent in charge promptly.

14.5. Upon presentation of proper credentials and at reasonable times, the secretary is to be given access to all records relating to the generation, transportation, storage, treatment or disposal of infectious medical waste in the possession of any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled such waste. The secretary is to be furnished with copies of all such records or given the records for the purpose of making copies. If the secretary, upon inspection, investigation or through other means, observes or learns of a violation or probable violation of relevant State law or this rule, he or she is authorized to issue subpoenas and subpoenas duces tecum and to order the attendance and testimony of witnesses and to compel the production of any books, papers, documents, manifests and other physical evidence pertinent to such investigation or inspection.

§64-56-15. Enforcement Orders; Related Hearings; Permit Reinstatement.

Enforcement orders and related hearings are required to be conducted according to the provisions of W. Va. Code §§~~20-5E-14~~ 22-18-15, 20-5J-8 and 29A-5-1 et seq. as outlined in Sections 15.1 and 15.2 of this rule.

15.1. If the secretary, upon inspection, investigation or through other means observes, discovers or learns of a violation of the provisions of this rule or relevant State law or of any order or permit issued under this rule or such law by the secretary, he or she may:

15.1.a. Issue an order stating with reasonable specificity the nature of the violation and requiring compliance immediately or within a specified time. An order under this section includes, but is not limited to, any or all of the following: orders suspending, modifying or revoking permits, orders requiring a person to take remedial action, or cease and desist orders;

15.1.b. Seek an injunction in accordance with W.Va. Code §20-5J-9(b);

15.1.c. Institute a civil action in accordance with W. Va. Code §20-5J-9(a); or

15.1.d. Request the attorney general or the prosecuting attorney of the county in which the alleged violation occurred to bring a criminal action in accordance with W. Va. Code ~~§20-5E-15~~ 22-18-16.

15.2. Any person issued a cease and desist order may file a notice of request for reconsideration with the secretary not more than seven (7) days from the issuance of such order and shall have a hearing before the secretary contesting the terms and conditions of such order within ten (10) days of the filing of such notice of a request for reconsideration. The hearing is conducted as required by State law and Section 19 of this rule. The filing of a notice of request for reconsideration shall not stay or suspend the execution or enforcement of such cease and desist order.

15.3. Any person whose permit issued under this rule has been suspended or revoked may, at any time, make application for reinstatement of the permit. After receipt of a written request, including a signed statement by the applicant that in his or her opinion the conditions causing the suspension of the permit have been corrected, the secretary shall make an inspection or investigation of the applicant's operation. If the applicant complies with the provisions of this rule, the permit shall be reinstated.

15.4. The secretary may suspend or revoke a permit if the permit has been obtained by means of fraud, deceit or material misrepresentation.

§64-56-16. Criminal Penalties.

. Criminal penalties are applied according to the provisions of W. Va. Code ~~§20-5E-15~~ 20-18-16 as described in this Section.

16.1. If any person knowingly: (1) transports any infectious medical waste identified or listed under this rule to a facility which does not have a permit required by this rule; or (2) treats, stores or disposes of any such infectious medical waste either (A) without having obtained a permit required by this rule or (B) in knowing violation of a material condition or requirement of such permit, he or she is guilty of a felony, and, upon conviction thereof, is required to be fined not to exceed fifty thousand dollars (\$50,000) for each day of violation or to be confined in the penitentiary not less than one (1) nor more than two (2) years, or to receive both such fine and imprisonment or, in the discretion of the court, be confined in jail not more than one (1) year in addition to the above fine

16.2. If any person knowingly: (1) makes any false material statement or representation in any application, label, manifest, record, report, permit or other document filed, maintained or used for purposes of compliance with this rule; or (2) generates, stores, treats, transports, disposes of or otherwise handles any infectious medical waste identified or listed under this rule and who knowingly destroys, alters or conceals any record required to be maintained under this rule, he or she is guilty of a misdemeanor, and, upon conviction thereof, is required to be fined not to exceed twenty-five thousand dollars (\$25,000), or sentenced to imprisonment for a period

not to exceed one (1) year, or both fined and sentenced to imprisonment for each violation.

16.3. Any person convicted of a second or subsequent violation of Sections 16.1 and 16.2 of this rule, is guilty of a felony, and, upon such conviction, shall be confined in the penitentiary not less than one (1) nor more than three (3) years, or fined not more than fifty thousand dollars (\$50,000) for each day of violation, or both such fine and imprisonment.

16.4. Any person who knowingly transports, treats, stores or disposes of any infectious medical waste identified or listed pursuant to this rule in violation of Section 16.1 of this rule, or having applied for a permit pursuant to this rule and knowingly fails to include in a permit application any material information required pursuant to this rule and who thereby exhibits an unjustified and inexcusable disregard for human life or the safety of others and thereby places another person in imminent danger of death or serious bodily injury, is guilty of a felony, and, upon conviction thereof, is required to be fined not more than two hundred fifty thousand dollars (\$250,000) or imprisoned not less than one (1) year not more than four (4) years or to receive both such fine and imprisonment.

16.5. As used in Section 16.4 of this rule, the term "serious bodily injury" means:

16.5.a. Bodily injury which involves a substantial risk of death;

16.5.b. Unconsciousness;

16.5.c. Extreme physical pain;

16.5.d. Protracted and obvious disfigurement; or

16.5.e. Protracted loss or impairment of the function of a bodily member, organ or mental faculty.

§64-56-17. Civil Penalties.

Civil penalties are to be assessed according to the provisions of W. Va. Code §§~~20-5E-16~~ 22-18-17 and 20-5J-9 which are outlined in this section.

17.1. Any person who violates any provision of this rule or an order issued pursuant to this rule is subject to a civil administrative penalty, to be levied by the secretary, of not more than seventy-five hundred dollars (\$7,500) for each day of such violation, not to exceed a maximum of twenty-five thousand dollars (\$25,000).

17.2. In assessing any such penalty, the secretary is required to take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements as well as any other appropriate factors, such as: (1) the severity of serious physical harm most

likely to result, and if applicable, that did result, from the violation; (2) the extent to which the provisions of this rule were violated; and (3) any previous violations committed by the alleged violator. No assessment is to be levied pursuant to this subsection until after the alleged violator has been notified by certified mail or personal service.

17.2.a. The notice is required to include a reference to the section of the statute, rule, regulation, order or statement of permit conditions that was allegedly violated, a concise statement of the facts alleged to constitute the violation, a statement of the amount of the administrative penalty to be imposed and a statement of the alleged violator's right to an informal hearing.

17.2.b. The alleged violator has twenty (20) calendar days from receipt of the notice within which to deliver to the secretary a written request for an informal hearing. If no hearing is requested, the notice becomes a final order after the expiration of the twenty-day period. If a hearing is requested, the secretary is required to inform the alleged violator of the time and place of the hearing. The secretary may appoint an assessment officer to conduct the informal hearing and then make a written recommendation to the secretary concerning the assessment of a civil administrative penalty.

17.2.c. Within thirty (30) days following the informal hearing, the secretary is required to issue and furnish to the violator a written decision, and the reasons therefore, concerning the assessment of a civil penalty.

17.2.d. Within thirty (30) days after notification of the secretary's decision, the alleged violator may request a formal hearing in accordance with the provisions of W. Va. Code ~~§20-5E-19~~ 22-18-20 and Section 19 of this rule.

17.3. The authority to levy an administrative penalty is in addition to all other enforcement provisions of State law or this rule and the payment of any assessment is not deemed to affect the availability of any other enforcement provision in connection with the violation for which the assessment is levied: Provided, that no combination of assessments against a violator under this rule are to exceed twenty-five thousand dollars (\$25,000) per day of each such violation: Provided however, that any violation for which the violator has paid a civil administrative penalty assessed under this section may not be the subject of a separate civil penalty action under State law to the extent of the amount of the civil administrative penalty paid.

17.4. No assessment levied pursuant to Section 17.1 of this rule is due and payable until the procedures for review of such assessment as set out herein and in State law have been completed.

17.5. Any person who violates any provision of this rule, or order issued pursuant to this rule is subject to a civil penalty not to exceed twenty-five thousand dollars (\$25,000) for each day of such violation, which penalty is to be recovered in a civil action either in the circuit court wherein the violation occurs or in the circuit court of Kanawha County.

17.6. The secretary may seek an injunction, or may institute a civil action against any person in violation of any provisions of this rule, or order issued pursuant to this rule. In seeking an injunction, it is not necessary for the secretary to post bond nor to allege or prove at any stage of the proceeding that irreparable damage will occur if the injunction is not issued or that the remedy at law is inadequate. An application for injunctive relief or a civil penalty action under this section may be filed and relief granted notwithstanding the fact that all administrative remedies provided for in this rule have not been exhausted or invoked against the person or persons against whom such relief is sought.

§64-56-18. Imminent and Substantial Hazards; Orders; Penalties; Hearings.

18.1. Notwithstanding any provision of this rule to the contrary, the secretary, upon receipt of information, or upon observation or discovery that the handling, storage, transportation, treatment or disposal of any infectious medical waste may present an imminent and substantial endangerment to public health, safety or the environment, has the authority to:

18.1.a. Request the attorney general or the appropriate prosecuting attorney to commence an action in the circuit court of the county in which the hazardous condition exists to immediately restrain any person contributing to such handling, storage, transportation, treatment or disposal to stop such handling, storage, transportation, treatment or disposal or to take such other action as may be necessary; or

18.1.b. Take other action under this section including, but not limited to issuing such orders as may be necessary to protect public health and the environment.

18.2. Any person who willfully violates, or fails or refuses to comply with, any order of the secretary under Section 18.1 of this rule may, in an action brought in the appropriate circuit court to enforce such orders, be fined not more than five thousand dollars (\$5,000) for each day in which such violation occurs or such failure to comply continues.

§64-56-19. Administrative Due Process.

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

§64-56-20. Severability.

The provisions of this rule are severable. If any provision of this rule is held invalid, the remaining provisions shall remain in effect.

TABLE 64-56A.

**ANNUAL INFECTIOUS MEDICAL WASTE MANAGEMENT
FACILITY PERMIT AND OPERATOR REGISTRATION FEES**

Type of Facility	Fee
A. Hospitals (Non-Commercial Treatment Facilities)	
1 to 50 Beds	\$ 500.00
51 to 149 Beds	1,750.00
150 or More Beds	2,500.00
B. Commercial Infectious Medical Waste Management Facility	5,000.00
Small Commercial Infectious Medical Waste Management Facility for Sharps Only (As defined in Section 11.15 <u>provided for in Section 11.19</u> of this rule)	150.00
C. Transportation Vehicles (Each)	250.00
D. Commercial Storage and Transfer Facility	250.00
E. Other (Generating more than 50 pounds per month)	
1. Health Care Professionals	250.00
2. Independent Dialysis Centers	250.00
3. Independent Laboratories	250.00
4. Independent Rural Clinics	250.00
5. Nursing Homes	250.00
6. Other Long Term Care Facilities	250.00
7. Outpatient Surgery Centers	250.00
F. Incinerator Operator Registration	25.00
G. <u>Alternative treatment evaluation fee</u>	<u>500.00</u>