

WEST VIRGINIA
SECRETARY OF STATE

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #8

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APR 23 10 14 AM '93

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

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

Department of Commerce, Labor and Environmental Resources
AGENCY: Division Environmental Protection TITLE NUMBER: 47

CITE AUTHORITY WV Code §20-5N-8

AMENDMENT TO AN EXISTING RULE: YES NO

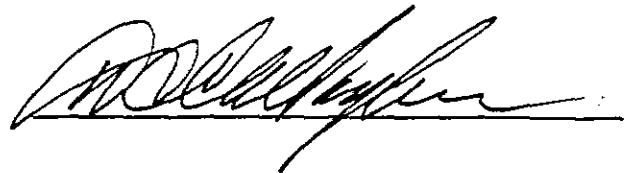
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 38C

TITLE OF RULE BEING PROPOSED: "Solid Waste Landfill Closure Assistance
Program Regulations"

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.



6.20

DATE:

FILED

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

APR 23 10 14 AM '93

FROM:

LEGISLATIVE RULE TITLE: "Solid Waste Landfill Closure Ass^{OFFICE OF WEST VIRGINIA} Regulations" ^{SECRETARY OF STATE}

1. Authorizing statute(s) citation § 20-5N-8 WV Code

2. a. Date filed in State Register with Notice of Hearing

N/A

b. What other notice, including advertising, did you give of the hearing?

N/A

c. Date of Hearing(s) N/A

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

Attached N/A No comments received

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

f. Name and phone number(s) of agency person(s) to contact for additional information:

G. Max Robertson, Chief 558-5929

Randy C. Huffman, Assistant Chief 558-7763

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 of a hearing for the taking of evidence and a general description of the issues to be decided.

No hearing was conducted, however, a public comment period was held.

b. Date of hearing: N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

**PREAMBLE TO AN AGENCY APPROVED RULE CONCERNING THE
SOLID WASTE LANDFILL CLOSURE ASSISTANCE PROGRAM REGULATIONS**

AGENCY: Department of Commerce, Labor and Environmental
Resources, Division of Environmental Protection.

REGULATION: Title 47, Series 38C, "Solid Waste Landfill
Closure Assistance Program Regulations."

AUTHORITY: West Virginia Code §20-5N-8.

ACTION: Filing of an agency approved Proposed Rule.

SUMMARY: During the 1991 Special Legislative Session, Senate Bill 18 was passed. The bill created Article 5N under Chapter 20 of the West Virginia Code. Today's filing proposes regulations to implement Article 5N (Solid Waste Landfill Closure Assistance Program).

During the 30-day comment period, DEP received comments from two parties. Attached are their original letters along with their comments and DEP's responses.

FILED

APR 23 10 14 AM '93

TITLE 47
LEGISLATIVE RULES
DIVISION OF ENVIRONMENTAL PROTECTION

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

SERIES 38C
COMMERCIAL SOLID WASTE LANDFILL CLOSURE ASSISTANCE PROGRAM
REGULATIONS

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TITLE 47
LEGISLATIVE RULES
DIVISION OF ENVIRONMENTAL PROTECTION

SERIES 38C
COMMERCIAL SOLID WASTE LANDFILL CLOSURE ASSISTANCE PROGRAM
REGULATIONS

47-38C-1. General.

1.1. Scope and Purpose - This legislative rule establishes requirements for the operation of the Landfill Closure Assistance Program pursuant to WV Code Chapter 20 Article 5N, as amended. Article 5N provides an application process for the permittee, sets conditions for application approval, provides guidance for interim status assistance, and establishes a prioritization procedure for assistance. This rule applies to any permittee who may desire closure assistance from the Division of Environmental Protection.

1.2. Authority - WV Code § 20-5N-8

1.3. Filing Date __

1.4. Effective Date __

1.5. Short Title: Closure Assistance Program

1.6. Incorporation by Reference - Whenever federal or state statutes or regulations are incorporated into these regulations by reference, the reference is to the statute or regulation in effect on July 1, 1992.

47-38C-2. Definitions.

2.1. "Cost of project" includes the cost of the services authorized in sections three and ten of WV Code Chapter 20 Article 5N, as amended, property, material and labor which are essential thereto, financing charges, interest during construction, and all other expenses, including legal fees, trustees', engineers' and architects' fees which are necessarily or properly incidental to the program;

2.2. "Director" means the director of the division of environmental protection of the department of commerce, labor and environmental resources, or his or her authorized representative;

2.3. "Landfill" means any solid waste facility for the disposal of solid waste on land, and also means any system,

facility, land, contiguous land, improvements on the land, structures or other appurtenances or methods used for processing, recycling or disposing of solid waste, including landfills, transfer stations, resource recovery facilities and other such facilities not herein specified. Such facility shall be deemed to be situated, for purposes of these regulations, in the county where the majority of the spatial area of such facility is located;

2.4. "Permittee" means a person who has or should obtain a permit for a commercial solid waste facility that is a landfill;

2.5. "Project" means the providing of closure assistance to one or more landfills under these regulations;

2.6. The definitions provided in WV Code Chapter 20 Article 5F Section 2, and the regulations promulgated thereunder, to the extent they are applicable, apply to these regulations.

47-38C-3. Closure Assistance Application.

3.1. Unless otherwise instructed by the director in writing, the permittee shall use the Application form attached (Appendix A).

3.2. The application may request the following information:

3.2.1. Name of Permittee;

3.2.2. Mailing Address of Permittee;

3.2.3. Name of Facility;

3.2.4. General Location of Facility;

3.2.5. Solid Waste Facility Permit No. or
Permit Application No., as applicable;

3.2.6. NPDES Permit No. and Effective Date or
Application No. or
General Permit No., as applicable;

3.2.7. Type of Bond in Effect, Amount, and Expiration
Date;

3.2.8. Financial Information

3.2.8.a The financial statement shall include income statements, balance sheets, statements of changes in financial position, and accompanying notes to such statements. The statements will cover the most recent accounting year and the two immediately preceding accounting years.

3.2.8.b It is required that these statements be Audited Statements provided by independent certified public accountants unless the director grants a waiver of these requirements pursuant to 3.2.8.d

3.2.8.c If the statements are supplied unaudited, they shall at a minimum contain the following information:

3.2.8.c.1 The income statements will contain such detail as to identify all sources of revenue and a reasonable breakdown of expenses including interest, depreciation and taxes.

3.2.8.c.2 The balance sheet's asset section will contain identification of all cash and investments, property, plant, and equipment, and other assets. The liabilities section will contain current accounts and notes receivable and a listing of all long term debt. The equity section will contain the beginning balance, current year changes and ending balance.

3.2.8.c.3 The statements of changes in financial position will identify the sources and uses of cash by the reporting entity.

3.2.8.c.4 The statements will be accompanied with supporting notes which explain and detail the major items of interest and make necessary disclosures.

3.2.8.c.5 Unaudited statements will be accompanied with supported by copies of filed federal income tax returns.

3.2.8.d At the discretion of the director, the above requirements or portions thereof may be waived for good cause. The waiver shall be requested and approved or denied in writing.

3.2.8.e The financial information section of these regulations may apply to all parties named in the original disclosure application as required in WV Code 20-5F-4(k).

3.2.9. Any other information from the permittee required by the director, in writing, in order to determine the permittee's acceptance into the program.

3.3. The application will be reviewed by the director and notification of acceptance or rejection will be sent to the permittee within a reasonable amount of time. If the application is rejected, the notice shall contain the reasons for the rejection.

3.4. If the permittee's application is rejected, the permittee shall have the opportunity to correct or remedy where the Director finds, in writing, that the conditions which are the basis for the Director's rejection can be corrected or remedied. The applicant may resubmit its application for closure assistance within 90 days after the date of receipt of the Director's notice of rejection and the deadline for application for landfill closure assistance will be extended for this period to allow for resubmission of the permittee's application.

3.5. All deadlines set forth in West Virginia Code Chapter 20 Article 5N Section 6 are applicable.

47-38C-4. Conditions for Closure Assistance Application Approval.

4.1. The applicant must currently have in his possession a valid landfill facility permit in compliance with the Solid Waste Management Act (WV Code Chapter 20 Article 5F) containing an approved closure plan for the landfill facility.

4.1.1. That landfill facility permit must contain, in the form of "major" or "minor" modifications, all changes in name, operation, ownership, or operator(s).

4.1.2. That landfill facility permit must contain, in the form of a modification, the landfill facility NPDES requirements of the Water Pollution Control Act (WV Code Chapter 20 Article 5A).

4.2. Bonding.

4.2.1. The applicant must have submitted the full amount of the bond required under 4.2.2 and received approval of the bond from the director.

4.2.2. The bonding requirements set forth in WV Code Chapter 20 Article 5F and in Section 3.13 of Title 47, Series 38, Solid Waste Management Regulations are applicable.

4.2.3. None of the requirements of Section 4.2.2 may be waived without written approval of the director.

4.3. Violations.

4.3.1. All closure-related DEP Notices of Violation(s) shall have been abated.

4.3.2. All closure-related DEP Civil Administrative Penalties shall have been paid, or reflected in a payment schedule contained in subsequently-issued Solid Waste Administrative Orders.

4.3.3. All terms and conditions of any prior closure-related Administrative Orders shall have been resolved.

4.3.4. All stipulated penalty amounts in any prior Administrative Orders shall have been paid, or reflected in a payment schedule contained in a subsequently-issued Administrative Order.

4.3.5. None of the requirements of Section 4.3 may be waived without written approval of the director.

4.4. Legalities.

4.4.1. All pending magistrate, Water Resources Board, State Court, Federal Court, or other legal actions must have been resolved.

4.4.2. None of the requirements of Section 4.4.1 may be waived without written approval of the director.

4.5. Closure Funds.

4.5.1. All funds available at the time of closure that have been dedicated to closure, as may have been required by the PSC, shall have been expended for closure, in compliance with Title 47 Series 38 Section 6, or donated to the Closure Cost Assistance Fund as outlined in WV Code Chapter 20 Article 5N Section 4(a).

4.6. Additional Closure Items.

4.6.1. The applicant shall have complied, or begun to comply with the following permit, or regulatory requirements, as outlined in Section 6 of Title 47, Series 38, Solid Waste Management regulations. These items are ineligible for coverage by closure assistance program:

4.6.1.a. Legal Advertisement

4.6.1.b. Notification to Users

4.6.1.c. Notification to Chief

4.6.1.d. Posting of Signs on the Fence

4.6.1.e. Denial of Entry/Restricted Access

4.6.1.f. Notification to Solid Waste Authority, State Solid Waste Management Board, etc.

4.6.1.g. Deed Notation

4.6.2. The Closure Assistance program shall also cover the payment of principal, premium, if any, and interest accrued with respect to any indebtedness, bonded or otherwise, outstanding with respect to any landfill scheduled for closure which was incurred in connection with the acquisition, construction or equipping landfills qualifying for assistance.

4.7. An approved application provides a basis for the chief to modify the permit in accordance with the provisions of Section 6 of Title 47, Series 38, Solid Waste Management Regulations in order to meet the requirements of the Closure Assistance Program.

4.8. Upon acceptance of a permittee into the Closure Assistance Program, access to the facility shall be given to the director.

47-38C-5. Interim Status Assistance.

5.1. The Director may establish maintenance contracts to maintain intermediate cover, water control structures, sediment control structures, surface water and ground water monitoring, gas management, leachate management and any other closure related requirements of WV Code Chapter 20 Article 5F and rules promulgated pursuant thereto. These contracts will be established for the purpose of assisting the permittee, who has an approved closure assistance application, in maintaining compliance with closure related requirements until final closure activities are initiated.

47-38C-6. Post Closure Assistance.

6.1. Unless otherwise specified by the director, all post closure monitoring, maintenance, sampling, testing, and water treatment will be conducted by the DEP.

47-38C-7. Contracting.

7.1. All funds expended from the Closure Assistance Fund for the purposes of fulfilling the requirements of WV Code Chapter 20 Article 5N will be in accordance with Department of Administration laws, rules, and procedures.

7.2. Landfill closure assistance provided by the Director shall be contingent upon the availability of revenues from the Closure Cost Assistance Fund.

47-38C-8. Final Closure Assistance Priority.

8.1. The Director shall establish the priority for final closure assistance by assessing landfill conditions as provided for by the utilization of the Priority Evaluation Matrix in Appendix B.

Closure Assistance Application

- 1) Name of Permittee: _____

- 2) Mailing Address
of Permittee: _____

- 3) Name of Facility: _____

- 4) General Location
of Facility: _____

- 5) Solid Waste Facility:
Permit No. _____ or Permit Application No. _____

- 6) NPDES:
Permit No. _____ Effective Date _____
or
Application No. _____
or
General Permit No. _____

- 7) Type of Bond Used: _____
Amount: _____
Expiration Date: _____

- 8) Financial data from Permittee (attached)

- 9) Any other information needed by the Director in order to
determine acceptance into the program (attached)

- 10) Any information deemed by the permittee to be relevant
(attached)

LANDFILL CLOSURE ASSISTANCE PROGRAM

PRIORITY EVALUATION MATRIX

LANDFILL NAME: _____
 COUNTY: _____
 USGS QUADRANGLE: _____
 LATITUDE: _____
 LONGITUDE: _____

	Low	High	Multiply By	Score
Potential Adverse Impact on Human Health & Safety	0 1 2 3 4 5 6 7 8 9 10		20	_____
Adverse Impact on Groundwater	0 1 2 3 4 5 6 7 8 9 10		15	_____
Adverse Impact on Surface Water	0 1 2 3 4 5 6 7 8 9 10		15	_____
Adverse Impact on Air Quality	0 1 2 3 4 5 6 7 8 9 10		15	_____
Degree of Surface Instability	0 1 2 3 4 5 6 7 8 9 10		10	_____
Adverse Impact on Improved Property	0 1 2 3 4 5 6 7 8 9 10		10	_____
Adverse Impact on Fish, Wildlife & Plant Habitat	0 1 2 3 4 5 6 7 8 9 10		10	_____
Potential for Development	0 1 2 3 4 5 6 7 8 9 10		5	_____
TOTAL SCORE				_____

 Signature of Evaluator & Date



DEPARTMENT OF COMMERCE, LABOR & ENVIRONMENTAL RESOURCES

OFFICE OF THE SECRETARY

State Capitol, Room R-151

Charleston, West Virginia 25305-0310

Telephone: (304) 558-3255

Fax No.: (304) 558-4983

GASTON CAPERTON
Governor

JOHN M. RANSON
Cabinet Secretary

August 17, 1992

Mr. David C. Callaghan, Director
Division of Environmental Protection
#10 McJunkin Road
Nitro, West Virginia 25143-2506

RE: Proposed Rule - Title 47, Series 38C (Solid Waste
Landfill Closure Assistance Program Regulations)

Dear Dave:

Pursuant to West Virginia Code 5F-2-2(a)(12), I hereby
consent to the proposal of the rule specified above.

You may attach a copy of this letter to your filing
with the Secretary of State as evidence of my consent.

Sincerely yours,

A handwritten signature in cursive script that reads "John M. Ranson".

John M. Ranson
Cabinet Secretary

JMR:mcl

FISCAL NOTE FOR AN AGENCY APPROVED RULE

Rule Title: Title 47, Series 38C, "Solid Waste Landfill Closure Assistance Program."

Type of Rule: XX Legislative Interpretive Procedural

Agency: Department of Commerce, Labor and Environmental Resources, Division of Environmental Protection.

Address: 1356 Hansford Street, Charleston, West Virginia 25301.

1. Effect of Proposed Rule	Annual			Fiscal Year	
	Increase \$	Decrease \$	Current \$	Next \$	Thereafter \$
- Personal Services					
- Current Expense					
- Repairs and Alterations			NO CHANGE		
- Equipment					
- Other					

2. Explanation of Above Estimates: This regulation implements the Solid Waste Landfill Closure Assistance Program imposed by Senate Bill 18 passed in October of 1991. All monies collected for an established assistance fund shall be from a fee imposed upon the disposal of solid waste. No new administrative expenditures are anticipated.

3. Objective of These Rules: The objective of this rule is to implement an assistance program that will be available to permittees of solid waste landfills that will facilitate the closure of these landfills in a timely and environmentally sound manner.

4. Explanation of Overall Economic Impact of Proposed Rule.

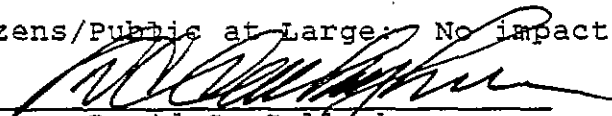
A. Economic Impact on State Government: No impact.

B.1. Economic Impact on Political Subdivisions: No impact.

2. Economic Impact on Specific Industries: No impact.

3. Economic Impact on Specific Groups of Citizens: No impact.

C. Economic Impact on Citizens/Public at Large: No impact.



 David C. Callaghan
 Director

Date: April 1, 1993

BOWLES RICE
McDAVID GRAFF & LOVE

ATTORNEYS AT LAW

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TELEPHONE 304-725-1535
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February 26, 1993

347-1726

HAND-DELIVERED

David Callaghan, Director
Division of Environmental Protection
Rule Comments
1356 Hansford Street
Charleston, West Virginia 25301

RECEIVED
FEB 29 9 25 AM '93
WASTE

Dear Mr. Callaghan:

On behalf of Waste Management, I submit the following comments with regard to the Closure Assistance Regulations. The Closure Assistance Regulations should require that either a professional engineer state that the facility as constructed can be closed with the previously approved plans without modification, or that the facility be required to submit a revised closure plan and have the revised closure plan approved.

The closure and post-closure costs of the facility should be reevaluated as part of the facility application. There is a high probability that closure and post-closure costs as presently estimated, are too low. A reevaluation of the closure and post-closure costs will allow a better determination of the total costs of property closing each facility.

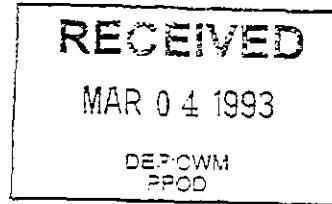
I trust that you will find these comments useful and if you should have any questions, please do not hesitate to contact me.

Very truly yours,

Leonard Knee
Leonard Knee

LK/mah
125689

February 26, 1993



DEP Rule Comments
1356 Hansford Street
Charleston, WV 25301

Attention: Public Information

RE: Proposed Rule -Title 47, Series 38C (Solid Waste Landfill Closure Assistance Program Regulation)

Dear Sir:

Pursuant to your request for comments on the Solid Waste Landfill Closure Assistance Program Regulation, RUST Environment and Infrastructure has prepared the following comments:

- The technical aspects of the closure procedures should be expanded, particularly for those site where contamination is a significant concern.
- A Work Plan should be prepared and reviewed by DEP to address groundwater and surface contamination. Additionally, on-site gas migration should be addressed.
- The closure design should be performed by a pre-qualified engineering firm and licensed professional engineer, P.E.
- The environmental investigation should be thorough to compliment the detail closure design and identify such requirements as:
 - a) Gas cut-off wall
 - b) Leachate collection quantities
 - c) Off-site groundwater contamination from leachate
 - d) Soil, sediment and erosion control measures
 - e) Slope stability analysis
- The final design should be reviewed and approved by DEP.
- The design engineers should prepare plans and specifications for bid of the closure construction.

DEP Rule Comments

Page 2

February 26, 1993

- The closure construction should be monitored by a qualified Construction/Quality Assurance Manager to assure the closure is properly performed and certified by a Licensed P.E.
- The cost estimates for site closures already submitted for the program appear low. The estimates do not appear to account for the following:
 - 1) Severe groundwater contamination
 - 2) Off-site gas migration (i.e. cut-off wall)
 - 3) In-depth detail design by Licensed P.E. (qualified engineer)
 - 4) Construction Management/Quality Assurance
 - 5) Construction Certification

Sincerely,

RUST ENVIRONMENT & INFRASTRUCTURE



Richard G. Habrukowich, Ph.D., P.E.
Regional Division Manager

RGH:jmm

C:DEP

COMMENTS FROM LEONARD KNEE

- ON BEHALF OF
WASTE MANAGEMENT

Comment: "The Closure Assistance Regulations should require that either a professional engineer state that the facility as constructed can be closed with the previously approved plans without modification, or that the facility be required to submit a revised closure plan and have the revised closure plan approved."

Response: A closure plan and an engineering design for closure are very different issues. The DEP intends to contract the closure design to qualified engineering firms. This requirement is outlined in Chapter 20 Article 5N §3(b)(1).

A closure plan does not necessarily consist of a detailed closure design. It is DEP's position that if a closure design already exists, then it will be reviewed and checked for accuracy. If none exists, then the DEP, according to the code, may pay for the closure design. Further, a closure design is not at all a complete design until it has been certified by a professional engineer. Therefore, to include this comment into the regulations, in DEP's opinion, would be redundant.

Comment: "The closure and post-closure costs of the facility should be reevaluated as part of the facility application. There is a high probability that closure and post-closure costs as presently estimated, are too low. A reevaluation of the closure and post-closure costs will allow a better determination of the total costs of property closing each facility."

Response: Closure and post-closure cost estimates were made part of the statewide closure plan which was submitted to the legislature by the DEP in January 1993. To require the applicant to provide DEP with more detailed cost estimates would not be cost effective. Cost estimates without detailed engineering designs are, at best, educated guesses. It is DEP's opinion that these facilities do not need to provide detailed cost estimates as part of their closure assistance application.

Comments from RUST Environment and Infrastructure

Comment: "The technical aspects of the closure procedures should be expanded, particularly for those site(s) where contamination is a significant concern."

Response: It is the DEP's position that the regulations are not the proper location for site specific technical details. Each site is different and will require different techniques to reclaim and/or remediate pollution problems. DEP feels that the site specific engineering design is the proper location for the technical aspects of closure procedures.

Comment: "A work plan should be prepared and reviewed by DEP to address groundwater and surface contamination. Additionally, on-site gas migration should be addressed."

Response: Once again, these issues will be addressed during the closure design phase of each individual site. Trying to incorporate site specific detail into the regulations is not a feasible plan.

Comment: "The closure design should be preformed by a pre-qualified engineering firm and licensed professional engineer, P.E."

Response: This issue is already adequately addressed in Title 47 Series 38, Solid Waste Management Regulations, §6.1.7. The closure assistance regulations do not supersede any item in Title 47 Series 38, in fact, the closure regulations fully incorporate Title 47 Series 38.

Comment: "The environmental investigation should be thorough to compliment the detail closure design and identify such requirements as:

- a) Gas cut-off wall
- b) Leachate collection quantities
- c) Off-site groundwater contamination from leachate
- d) Soil, sediment and erosion control measures
- e) Slope stability analysis"

Response: These items are inherently part of any landfill closure and are addressed in Chapter 20 Article 5N §3(b) of the West Virginia Code. The DEP felt there was no reason to be redundant.

Comment: "The final design should be reviewed and approved by DEP."

Response: §6.1.1 of Title 47 Series 38 already states the requirements for DEP's approval of the closure plan.

Comment: "The design engineers should prepare plans and specifications for bid of the closure construction."

Response: This is stated almost verbatim in DEP's statewide closure plan. DEP was not compelled to include such detail in the regulations.

Comment: "The closure construction should be monitored by a qualified Construction/Quality Assurance manager to assure the closure is properly performed and certified by a licensed P.E."

Response: Again, this requirement is already outlined in Title 47 Series 38, §6.1.7.

Comment: "The cost estimates for site closures already submitted for the program appear low. The estimates do not appear to account for the following:

1. Severe groundwater contamination
2. Off-site gas migration (i.e. cut-off wall)
3. In depth detail design by licensed P.E. (qualified engineer)
4. Construction Management/Quality Assurance
5. Construction certification"

Response: It is DEP's opinion that cost estimates have no place in these regulations. Further, the cost estimates which were made a part of the statewide closure plan are just that-estimates. These estimates were made using unit prices which have built-in allowances for design, certification, QA/QC, and other closure related structures. Allowances for groundwater remediation are impossible to make at this time.

Many of the comments on these regulations are addressed in the statewide closure plan. The plan offers a more comprehensive look at the intent of the program. Also, DEP's position on the drafting of these regulations was to be brief and non-restrictive and not be redundant by repeating already established laws and/or regulations.