BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
PETITION OF BIOMEDICAL TECHNOLOGY SOLUTIONS, INC., A Colorado Corporation, FOR ADJUSTED STANDARD FROM 35 Ill. Adm. Code Sec. 1422	)	**AS 08-006 (Adjusted Standard – Land)**

NOTICE OF FILING

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board
James R. Thompson Center
100 West Randolph Street
Suite 11-500
Chicago, IL 60601

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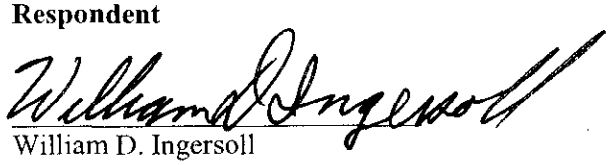
Attn: Neal H. Weinfield , Esq.
77 West Wacker Drive, Suite 2500
Chicago, Illinois 60601

PLEASE TAKE NOTICE that I have today filed with the office of the Clerk of the Pollution Control Board the **AMENDED RECOMMENDATION OF THE ILLINOIS EPA**, copies of which are herewith served upon you.

Respectfully submitted,

ILLINOIS ENVIRONMENTAL PROTECTION AGENCY,
Respondent



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Dated: December 26, 2007

BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	)	
	)	
PETITION OF BIOMEDICAL TECHNOLOGY	)	**AS 08-006**
SOLUTIONS, INC., A Colorado Corporation,	)	**(Adjusted Standard – Land)**
FOR ADJUSTED STANDARD FROM	)	
35 Ill. Adm. Code Sec. 1422	)	

AMENDED ILLINOIS EPA RECOMMENDATION

The ILLINOIS ENVIRONMENTAL PROTECTION AGENCY ("Illinois EPA"), by its attorney William Ingersoll, hereby submits its Amended Recommendation in the above captioned matter. The only modification is to correct exhibit references in paragraph 14, and attach those exhibits that were inadvertently omitted. This filing is submitted pursuant to Section 35 of the Illinois Environmental Protection Act ("EPAct") [415 ILCS 5/35 (2006)] and 35 Ill. Adm. Code 104 *et seq.* For the reasons outlined below, the Illinois EPA recommends that this petition be GRANTED conditionally.

I. INTRODUCTION

1. On June 28, 2007, Biomedical Technology Solutions, Inc. ("Petitioner"), filed a petition for Variance ("Variance") requesting relief from the Initial Efficacy Test ("IET") within 35 Ill. Adm. Code 1422.124(a). (Variance at 3)

2. According to the Variance, relief was sought "... to demonstrate the effectiveness of its device by conducting the [Initial Efficacy Test] using the Brown Indicator... (ATCC 9372) in place of ATCC 19659 as required by statute." (Variance at 3)

3. A July 28, 2007, Board Order considering the petition noted that Petitioner "...appears to be seeking more permanent relief more generally provided by an adjusted standard under Section 28.1 of the [EPAct]" and further noted that for Petitioner to seek temporary relief under a variance, it must provide a compliance plan that indicated how it will comply with the rule of general applicability when the variance expires. The Board found the petition failed to meet the necessary requirements under 35 Ill. Adm. Code 104.204 and directed Petitioner to file an amended petition by August 27, 2007, or the petition would be deemed dismissed. (Exh. 1)

   The Pollution Control Board ("Board") on July 26, 2007, found that the petition for Variance did not meet the content requirements of the Board's regulations. Petitioner was allowed the opportunity to file an amended petition by August 27, 2007. If not filed, the Board would dismiss the Variance petition and close the docket.

4. The Petitioner did not file an amended Variance petition. Thus, on September 20,

2007, the Board dismissed the petition for Variance and closed the docket. (Exh. 2)

5. On November 28, 2007, Petitioner filed a petition for Adjusted Standard ("petition or pet.") with the Board. The Illinois EPA received a copy of this pleading on November 30, 2007.

6. Within the Adjusted Standard, Petitioner notes that it manufactures a countertop medical waste treatment device, the Demolizer ®, and seeks a technology-specific adjusted standard from 35 Ill. Adm. Code Sec. 1422. (Pet. at 1)

II. INVESTIGATION

7. Notice of the petition, pursuant to Section 28.1 of the EPAct and Section 104.408 of the regulations, has been published in a newspaper of general circulation.

8. To date, Respondent has not received a citizen inquiry.

9. The Illinois EPA and Petitioner have engaged in discussions over this matter.

10. The Illinois EPA notes that the copy of the Adjusted Standard served on it was miss captioned as a pleading in the form of a Variance petition which identifies the Illinois EPA as a Respondent. Such is not the case. Further, the Illinois EPA took the liberty of captioning the pleading as a request for relief from 35 Ill. Adm. Code Sec. 1422 as noted in the Adjusted Standard at page 1. However, as discussed below, such relief is overly broad.

11. The Illinois EPA further notes that the petition provides that "BMTS and the Illinois [EPA] have agreed to waive a hearing for this petition." (Pet. at 1, footnote 1) Though the Illinois EPA and Petitioner discussed the hearing requirement, the Illinois EPA did not agree to waive a hearing since it is not within the Illinois EPA's authority to waive a hearing. The Board regulations (35 Ill. Adm. Code 104.422) discussed provides guidance relative to a public hearing and one may be held if requested by the Petitioner, any person, or at the Board's discretion. In addition, one must be held if the petition seeks relief from certain regulations. The Illinois EPA does not request a hearing in this matter.

III. FACTS PRESENTED IN THE PETITION

12. Petitioner starts off its petition requesting the Board "... for an Adjusted Standard from a provision of 35 IAC 1422. Later in this paragraph, Petitioner clarifies that relief is sought since Section 1422 requires the use of a particular microorganism, *Bacillus subtilis* (ATCC 19659), to determine the initial efficacy of the technology." (Pet. at 1) Petitioner concludes its petition by providing that it seeks relief "... from the provisions of 35 IAC 1422.Table B ... ." (Pet. at 32) Generally speaking,

Adjusted Standard petitions are filed from specific relief from rules of general applicability. In this case, Petitioner does not request specific relief within its discussion of the matter, choosing to request general relief from Section 1422. In such a case, the Illinois EPA would recommend that, if the Board provides relief, that relief by limited to the requirement that *Bacillus subtilis* (ATCC 19659) alone may be used, which would be specific relief to 35 Ill. Adm. Code Section 1422, Appendix A, Table B(1). Again, relief should not be granted, as plead, from Section 1422 in general.

13. Within the Introduction, Petitioner provides that "... the waste [that is] sterilized and rendered into a non-recognizable solid waste [ ] can then be disposed of as any other refuse." (Pet. at 2) The Illinois EPA would suggest that treated PIMW would still be an "industrial process waste" and a "special waste" under Illinois regulations and not be like any other "solid waste" or "refuse."

14. Petitioner states at various points within the petition that "[t]he technology is formally approved or meets statutory requirements in 46 states." (Pet. at 2, See also reference to 46 states at pages: 3, 5, 11, 15, and 27) Initially, some states do not specify a particular strain of indicator and some states do not regulate such testing at all. Some states, such as Texas, require that a commercially available species be used that can achieve a "kill ratio" of 99.99%. States such as Alabama, West Virginia, Virginia and Utah do recognize expressly ATC19659 as an appropriate bacterial spore. (Exh. A) Moreover, it is possible, though more review would be necessary to confirm that States such as Arizona and Delaware which have issued approved the use of the KSU test reviewed more information regarding the Demolizer ® than simply a recitation of whether ATCC 19659 and ATCC 9372 are similar. Finally, this claim (that ... "[c]urrently, out of the 46 states that have approved the Demolizer ® or for which the Demolizer ® meets statutory requirements ...") is suspect, in general, since such a contention is that of the 46 states, the Demolizer ® "meets statutory requirements" which falls short of stating that the unit is approved in 46 states. For example, according to Petitioner's web site (www.bmtscorp.com) the Demolizer ® system is either formally approved or meets the requirements for medical waste treatment and disposal in 46 U.S. states. (www.bmtscorp.com/usmap.shtm) Yet, interestingly, the state of Illinois is listed as one of the states "approved or meet[ing] state requirements" and not as a state within which "approval [is] in process." (Exh. B)

15. Likewise, Petitioner provides that ATCC 9372 "... is the scientifically-recognized standard in 46 states ... ." (Pet. at 3) This contention is difficult to verify and would seem suspect. If again Illinois is within the 46 number continually used by Petitioner, the statement is not correct, to date. As noted within Attachment A to the Petition, BMTS provides that the Demolizer ® is formally approved in only 22 states (20 states plus Arizona and Delaware) and that 23 states do not formally review technologies for onsite treatment of low volumes of medical waste. Thus, it is difficult to reconcile that 46 states scientifically-recognize ATCC 9372 when,

according to Attachment A, 23 states do not formally review technologies. However, more information could be provided to bolster this contention[1]. Additionally, 1 state appears to be missing (22 states alleged to have formally approved and 23 states alleged to meet or exceed regulatory requirements = 45 states)

15. Similarly, Petitioner offers that "[c]urrently, out of the 46 states that have approved the Demolizer ® or for which the Demoizer ® meets statutory requirements, Illinois is the only state that has required use of the Chemical Indicator in the IET for the Demolizer ® technology rather than the Certified or Dry Heat Indicator for the validation of the dry heat sterilization technology." (Pet. at 5) This statement is not entirely correct in that, as noted within the petition, Arizona and Delaware have regulations providing that ATCC 19659 be used. (Pet. at 11 – "... three states specifically identify [ATCC 19659] in their regulations for use in validation procedures: Arizona, Illinois and Delaware."]

16. The Illinois EPA would also like to clarify several instances where Petitioner has alleged Illinois EPA's position. For example, at page 6 of the petition, Petitioner alleges **"[b]ased on all of this information, the Agency has agreed to recommend to the Board that it grant this Petition for an Adjusted Standard."** (Pet. at 15 – bold original, yet significance of such is unknown) The Illinois EPA's agreement to these contentions is not present within the documents provided in the petition and the Illinois EPA would like the opportunity to make its own conclusions and recommendations known rather than having them thrust upon them. No agreement was made regarding a recommendation prior to a pleading being filed and reviewed.

Additionally, Petitioner provides that Bill Ingersoll of the Illinois EPA "... recognized that the Yellow Indicator was not commercially available [footnote 9]." (Pet. at 13) Such a statement is not contained within Mr. Ingersoll's e-mail of June 4, 2007. To the contrary, Mr. Ingersoll provides simply that "... I am told that while this strain (ATCC 19659) may not be 'off the shelf' at this time, it can still be purchased." (Pet. Exh. E) The statement of Mr. Ingersoll is far from the statement offered. Further adrift from anything Mr. Ingersoll stated in his e-mail is footnote nine, which accompanies the above language attributed to Mr. Ingersoll, and provides clarification of what Petitioner contends to be an obstacle to its use of ATCC 19659. None of footnote 9 can fairly be placed into the brief discussion contained in the June 4, 2007 e-mail.

This same paragraph, Petitioner offers that "[p]ursuant to the suggestion of Mr. Ingersoll, BMTS filed a Variance Petition on or about June 24, 2007." (Pet. at 13) Petitioner filed a Variance petition, this is true. However, the Illinois EPA suggested, in writing, both on January 5, 2007 and April 4, 2007, that Petitioner had

[1] Attachment A to the Petition includes a letter dated September 28, 2007, indicating that it was written in response to a conversation with Kyle Davis of the Illinois Pollution Control Board. Mr. Kyle Davis is a counsel with the Illinois EPA and not with the Board. The Illinois EPA is unaware of any discussions between the Board and Petitioner.

options to use ATCC 19659 or to seek an Adjusted Standard. (Pet. Exh. B and D)

IV. STATUTORY CRITERIA

STANDARD FROM WHICH ADJUSTED STANDARD IS SOUGHT
35 Ill. Adm. Code Section 104.406(a)

17. The Board promulgated the requirements of 35 Ill. Adm. Code Section 1422 Design and Operation of Facilities for facilities treating potentially infectious medical wastes in 1993. As of June 21, 1993, the regulations stated:

> a) The manufacturer, owner or operator of a treatment unit shall conduct an Initial Efficacy Test, pursuant to Appendix A of this Part, for each model prior to its operation. ...
>
> b) The Initial Efficacy Test must be conducted by the use of Options 1, 2 or 3 of Appendix A of this Part, ...
>
> Appendix A provides:
>
> ... This Option 3 is for a treatment unit that uses thermal treatment and maintains the integrity of the container of indicator microorganism spores (e.g., autoclaves and incinerators). ...
>
> Appendix A, Table B, provides:
>
> Section1422.TABLE B Indicator Microorangisms
> 1. Bicillus subtilis (ATCC 19659) ...

Petitioner conducted testing of its medical waste treatment device using *Bacillus subtilis* var. *niger*, ATCC 9372 in place of *Bicillus subtilis,* ATCC 19659, as required by Section 1422, Appendix A, Table B. Petitioner now seeks an Adjusted Standard.

STATEMENT OF IMPLEMENTATIOIN OF FEDERAL REQUIREMENTS
35 Ill. Adm. Code 104.406(b)

18. This regulation of general applicability was not promulgated to implement, in whole of in part, the requirements of the CWA (33 USC 1251 et seq.), CAA (42 USC 7401 et seq.), or the State programs concerning RCRA, UIC or NPDES [415 ILCS 5/28.1].

LEVEL OF JUSTIFICATON
35 Ill. Adm. Code 104.406(c)

19. The regulations do not specify a level of justification or other requirements.

DESCRIPTION OF PETITIONER'S ACTIVITY
35 Ill. Adm. Code 104.406(d)

20. Petitioner intends to sell its product throughout the State of Illinois.

DESCRIPTION OF COMPLIANCE EFFORTS AND ALTERNATIVES
35 Ill. Adm. Code 104.406(e)

21. Petitioner offers that "[u]nder the Agency's current interpretation of the Board's regulations, it is impossible for BMTS to achieve immediate compliance, which could take as long as two and a half years due to the time and resources required to grow and certify a Chemical Indicator to the same standards already demonstrated in the KSU Efficacy Test." (Pet. at 17) It is questionable what significance should be attributed to the statement that it is impossible to achieve "immediate compliance." Petitioner is not faced with an issue of immediate compliance other than one created by its own conduct. In essence, Petitioner seeks review of it not complying with a regulatory requirement that it never intends to comply with. Petitioner, simply put, does not want to repeat the efficacy test it chose to perform with another indicator spore with those required, since 1993, under Illinois law.

22. Petitioner also offers that "immediate compliance would impose an arbitrary and unreasonable hardship." This standard is far more appropriate for seeking a Variance. However, the Illinois EPA will address the basic argument presented.

At the heart of Petitioner's claim for relief is the fact that Petitioner has already done a test and does not wish to re-test. For such a contention to be weighed equitably you need to review the circumstances surrounding the claim that it should not be required to re-test. Illinois regulations relative to which strain of indicator spore to used were enacted following a long regulatory process. The Board set the compliance date of June 21, 1993 for its regulations. Thus, for over 14 years the regulatory standards have been apparent for compliance with Illinois law. Petitioner conducted its testing in 2006. This testing was 13 years following the enactment and compliance deadline for Illinois law.

Additionally, if anything, the Illinois EPA's correspondence notes that the ATCC 19659 strain spore is commercially available. Petitioner's contention that it is not commercially available is troubling since the spore is available. Petitioner's issue with the spore is the fact that it will be require to purchase the strain, populate certified cultures and then re-test. Yet, as noted above, and as provided for within the petition, Illinois law required use of ATCC 19659 years long prior to Petitioner contracting for a test to be preformed.

There is no doubt that it will be more costly to do the IEF with the ATCC 19659. However, you have to answer the question why? The reason it is more costly is because Petitioner did not use the ATCC 19659 strain in the first place.

Moreover, this is not an issue relative to availability of the required spore, it is a contention that such costs would have to be spread to consumers in the price of the product. (Pet. at 21) This argument, is not unique to this matter, and as such should not be persuasive in itself.

The Board and the Illinois EPA should not be responsible for Petitioner's choice to use a spore which does not comply with long standing regulatory requirements. The existence of this ATCC issue was apparent to Petitioner, and was considered by Petitioner's consultant at Kansas State University. (Pet. at 8) Petitioner, though its consultant, chose to use a spore that was similar to that required by a number of states. Again, even arguendo if the spores are 99.8% similar in their genetic material, the difference between them was the cost to culture them and certify the population. (Pet. at 8) A choice to use the ATCC 9372 was purely elective and considered. Thus, the cost spreading of the need to use ATCC 19659 (which is overwhelmingly recognized as an appropriate spore for this type of testing) would have been far easier, and spread over far more units, had Petitioner chosen to use the spore identified in many states as an appropriate spore.

Is the time required to comply a factor? Petitioner posits that it could take a total time from of up to two years to cultivate a population. (Pet. at 21) However, the two year time frame surely must have been considered in Petitioner's initial decision to use the ATCC 9372 strain in place of the ATCC 19659 strain. Thus, it is difficult to assert that it will take Petitioner additional time to comply with Illinois law when Petitioner itself determined long before the filing of this pleading to accept the consequences of seeking approval for its use of a spore strain that did not comply with the express language within several state statutes. Additionally, the cost of time to sell these units in Illinois surely must have been considered prior to the filing of this petition.

Petitioner is not economically situated in a unique position as compared to others who would seek to comply with Illinois law. Other than the fact that Petitioner chose to proceed using ATCC 9372 in place of ATCC 19659, Petitioner is situated no differently than any other manufacturer of a medical waste treatment unit who wanted to certify a unit's IET. The costs to be born by use of ATCC 19659 by Petitioner, and indeed the time, would be the same for any manufacturer. The regulations do not arbitrarily or adversely affect Petitioner in this manner. The regulation does not impact this Petitioner more adversely or arbitrarily than any other person subject to an IET.

PROPOSED ADJUSTED STANDARD

35 Ill. Adm. Code 104.406(f)

23. The Illinois EPA notes the language proposed by Petitioner in at page 22 of the Petition, but can not agree to such. In the Illinois EPA's opinion, this Adjusted Standard petition would not be an appropriate mechanism to alter the rule of general applicability as to others, and as such, the general amendment proposed to Section 1422, Appendix A, Table B is not correct. Additionally, the Illinois EPA is not sure what the reference to it means within the last paragraph of Petitioner's Petitioner in Section IX of page 22. The phrase "... the Agency has been acknowledged meets ..." is incomplete and adds nothing to the rationale presented.

Provided the Board agrees to grant Petitioner's Adjusted Standard in this matter, the Illinois EPA would propose the following language for inclusion in the Board's Order in this matter:

"The Board grants Petitioner an Adjusted Standard, as presented in In the Matter of: Petition of Biomedical Technology Solutions, Inc., AS 08-006, from the requirement that *Bicillus subtilis* (ATCC 19659) be used in an Initial Efficacy Test under Section 1422, Appendix A, Table B(1) upon the condition that a appropriate test is preformed using *Bacillus subtilis* var. *niger* (ATCC 9372) and the results of such test comply with the requirements of this Part."

IMPACT ON THE ENVIRONENT
35 Ill. Adm. Code 104.406(g)

24. The Illinois EPA does not take issue generally with the representations made by Petitioner concerning environmental impact.

JUSTIFICATION FOR PROPOSED ADJUSTED STANDARD
35 Ill. Adm. Code 104.406(h)

25. The Burden of Proof contained at Section 104.426 states those matters the Board should consider in rendering a decision regarding a petition for Adjusted Standard. (See also EPAct: 415 ILCS 5/27(a)) The Illinois EPA would agree with Petitioner that the scholarly information provided establishes that the use of ATCC 9372 is consistent with present practice in testing dry-heat resistance. As such, the Board could find that factors relating to the Petitioner are substantially and significantly different from the factors relied upon by the Board in adopting the general regulations applicable to the Petitioner, and as such, grant an Adjusted Standard based upon this rationale.

CONSISTENCY WITH FEDERAL LAW
35 Ill. Adm. Code 104.406(i)

26. No issues regarding compliance with Federal law were identified during the review of this matter.

WAIVER OF HEARING
35 Ill. Adm. Code 104.406(j)

27. As stated above, the Illinois EPA does not request a hearing in this matter. Should the Board determine that a hearing is necessary, the Illinois EPA will participate.

V. RECOMMENDATION

A thorough review of the petition for relief was made by Illinois EPA technical staff. The Illinois EPA concludes that sufficient justification is presented to allow Petitioner to be granted an Adjusted Standard regarding the use of ATCC 9372 in an Initial Efficacy Test. The Illinois EPA recommends that the Board conditionally grant Petitioner its Adjusted Standard as presented in In the Matter of: Petition of Biomedical Technology Solutions, Inc., AS 08-006, from the requirement that *Bicillus subtilis* (ATCC 19659) be used in an Initial Efficacy Test under Section 1422, Appendix A, Table B(1), upon the condition that a appropriate test is preformed using *Bacillus subtilis* var. *niger* (ATCC 9372) and the results of such test comply with the requirements of this Part.

Based upon the forgoing, the Illinois EPA recommends that the Board conditionally GRANT Petitioner's petition for Adjusted Standard.

Respectfully submitted,

ENVIRONMENTAL PROTECTION AGENCY
OF THE STATE OF ILLINOIS

By: William D. Ingersoll

William D. Ingersoll
Division of Legal Counsel

DATED: December 26, 2007
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Welcome to the
Alabama Department of Environmental Management

ADEM

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Departmental Forms

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This list is detailed by number of the form.

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Form Number	Form Name PDF Version	Form Name Word or Excel Version	
8	Groundwater System Monthly Operational Data Report	Groundwater System Monthly Operational Data Report	
52	Registration Form for the Construction, Installation, or Modification of an Incinerator	Registration Form for the Construction, Installation, or Modification of an Incinerator	
60	Notification of Intent to Drill a Water Well	Notification of Intent to Drill a Water Well (This form is not available in a Word or Excel Format)	
103	Operating Permit Application Facility Identification Form	Operating Permit Application Facility Identification Form	
104	Permit Application for Indirect Heating Equipment	Permit Application for Indirect Heating Equipment	
105	Permit Application for Manufacturing or Processing Operation	Permit Application for Manufacturing or Processing Operation	
106	Permit Application for Waste Disposal	Permit Application for Waste Disposal	

EXHIBIT A

107	Permit Application for Stationary Internal Combustion Engines	Permit Application for Stationary Internal Combustion Engines	
108	Permit Application for Loading and Storage of Organic Compounds	Permit Application for Loading and Storage of Organic Compounds	
109	Permit Application for Volatile Organic Compound Surface Coating Emission Source	Permit Application for Volatile Organic Compound Surface Coating Emission Source	
110	Permit Application for Air Pollution Control Device	Permit Application for Air Pollution Control Device	
112	Permit Application for Solvent Metal Cleaning	Permit Application for Solvent Metal Cleaning	
166	Joint Application and Notification U. S. Department of Army, Corps of Engineers Alabama Department of Environmental Management	Joint Application and Notification U. S. Department of Army, Corps of Engineers Alabama Department of Environmental Management	C
184	Seal Gap Test Form	Seal Gap Test Form	
185	Purchase Water System Monthly Operation Report	Purchase Water System Monthly Operation Report	
186	State Indirect Permit Application	State Indirect Permit Application	
187	NPDES Permit Application Supplementary Information	NPDES Permit Application Supplementary Information	
188	NPDES Permit Application Semi-Public and Private Facilities	NPDES Permit Application Semi-Public and Private Facilities	
193	Application For Alabama Well Driller's License	Application For Alabama Well Driller's License (This form is not available in a Word or Excel Format)	
197	Air Permit Application for Gasoline Dispensing Facilities	Air Permit Application for Gasoline Dispensing Facilities	
198	Gasoline Transport Tank Truck Application	Gasoline Transport Tank Truck Application	
242	Filter Plant Monthly Operational Data Report	Filter Plant Monthly Operational Data Report	
257	Stabilization Lagoon Inspection Report	Stabilization Lagoon Inspection Report	C
259	Application for Approval to Use a Water Supply Well	Application for Approval to Use a Water Supply Well	

278	Disposal Approval Request	Disposal Approval Request	
279	Notification for Underground Storage Tanks	Notification for Underground Storage Tanks	
283	Notification for Above Ground Storage Tanks	Notification for Above Ground Storage Tanks	
300	Solid Waste Profile Sheet	Solid Waste Profile Sheet	
305	Permit Application Solid Waste Disposal Facility Construction/Demolition Landfill	Permit Application Solid Waste Disposal Facility Construction/Demolition Landfill	
309	Cargo Tank Tightness Test Report	Cargo Tank Tightness Test Report	
310	Notice of Temporary Closure	Notice of Temporary Closure	
311	Alternative Analysis	Alternative Analysis	
312	Calculation of Total Annualized Project Cost for Public-Sector Projects	Calculation of Total Annualized Project Cost for Public-Sector Projects	
313	Calculation of Total Annualized Project Cost for Private – Sector Projects	Calculation of Total Annualized Project Cost for Private – Sector Projects	
314	ADEM Baseline Monitoring Report Submittal Form	ADEM Baseline Monitoring Report Submittal Form	
315	ADEM Field Operation Division NPDES Individual Permit Application	ADEM Field Operation Division NPDES Individual Permit Application	C
316	Alabama Coastal Area Management Program Application for Approval of a Non-Regulated Use ADEM Adminst4rative Code Rule 335-8-1-.11 Groundwater Extraction 50 GPM or Greater	Alabama Coastal Area Management Program Application for Approval of a Non-Regulated Use ADEM Adminst4rative Code Rule 335-8-1-.11 Groundwater Extraction 50 GPM or Greater	C
317	Alabama Hazardous Waste/Used Oil Transporter Permit Application	Alabama Hazardous Waste/Used Oil Transporter Permit Application	
318	Alabama Tank Trust Fund Cost Proposal Form	Alabama Tank Trust Fund Cost Proposal Form	
319	Alabama Tank Trust Fund Payment Request Form	Alabama Tank Trust Fund Payment Request Form	
320	ALG610000 & ALG490000 Authorization Termination Request and Certification	ALG610000 & ALG490000 Authorization Termination Request and Certification	C

	This form is replaced by Form # 499	This form is replaced by Form # 499	
321	ALG610000 & ALG490000 Inspection Report and BMP Certification This form is replaced by Form # 500	ALG610000 & ALG490000 Inspection Report and BMP Certification This form is replaced by Form # 500	C
322	ALG610000 & ALG490000 Noncompliance Notification Report This form is replaced by Form # 501	ALG610000 & ALG490000 Noncompliance Notification Report This form is replaced by Form # 501	C
323	Alternative Medical Waste Treatment Technology Equipment Approval Application	Alternative Medical Waste Treatment Technology Equipment Approval Application	
324	Annual Certification Form for Discharges Associated with Petroleum Storage and Handling Areas	Annual Certification Form for Discharges Associated with Petroleum Storage and Handling Areas	
325	Annual Compliance Statement Form	Annual Compliance Statement Form	
326	Annual Statistical Inventory Reconciliation (SIR) Report Form	Annual Statistical Inventory Reconciliation (SIR) Report Form	
327	Application for a Permit for the Construction of a Motel, Hotel, or Other Multi-Unit Development on a Property Intersected by the Construction Control Line in the Alabama Coastal Area	Application for a Permit for the Construction of a Motel, Hotel, or Other Multi-Unit Development on a Property Intersected by the Construction Control Line in the Alabama Coastal Area	C
328	Application for a Permit for the Construction of Single Family Dwellings, Duplexes, or Other Similar Structures on Properties Intersected by the Construction Control Line in the Alabama Coastal Area	Application for a Permit for the Construction of Single Family Dwellings, Duplexes, or Other Similar Structures on Properties Intersected by the Construction Control Line in the Alabama Coastal Area	C
329	Application for Approval of a Non-Regulated Use in the Alabama Coastal Area Developments and Subdivisions of Property Greater then 5 Acres in Size	Application for Approval of a Non-Regulated Use in the Alabama Coastal Area Developments and Subdivisions of Property Greater then 5 Acres in Size	C

330	Application for Name Change or Transfer of Permit Solid Waste Disposal Facility	Application for Name Change or Transfer of Permit Solid Waste Disposal Facility	
331	Bulk (Gasoline) Plant Application	Bulk (Gasoline) Plant Application	
332	Cathodic Protection Monitoring Form for Impressed Current Systems	Cathodic Protection Monitoring Form for Impressed Current Systems	
333	CBM NPDES Stormwater Discharge Monitoring Report	CBM NPDES Stormwater Discharge Monitoring Report	C
334	CBM Toxicity Test Report Summary	CBM Toxicity Test Report Summary	C
335	Chemical Monitoring Data Report	Chemical Monitoring Data Report	
336	Chemical Monitoring Waiver Application	Chemical Monitoring Waiver Application	
337	Chemical Sampling Chain of Custody Form	Chemical Sampling Chain of Custody Form	
338	Clean Water State Revolving Fund (CWSRF) Construction Report Form	Clean Water State Revolving Fund (CWSRF) Construction Report Form (This form is not available in a Word or Excel Format)	
339	Clean Water State Revolving Fund (CWSRF) Loan Application Form	Clean Water State Revolving Fund (CWSRF) Loan Application Form	
340	Clean Water State Revolving Fund (CWSRF) Preapplication Form	Clean Water State Revolving Fund (CWSRF) Preapplication Form	
341	Clean Water State Revolving Fund (CWSRF) Supplemental General Conditions	Clean Water State Revolving Fund (CWSRF) Supplemental General Conditions	
342	Coal Permit Precipitation Event Discharge Limitations Exemption Claim Report	Coal Permit Precipitation Event Discharge Limitations Exemption Claim Report	C
343	Coalbed Methane Stormwater Inspection Summary Report	Coalbed Methane Stormwater Inspection Summary Report	C
344	Coalbed Methane Temporary Pit Wastewater Land Application Certification Report	Coalbed Methane Temporary Pit Wastewater Land Application Certification Report	C
345	Community Public Notification Certification Form	Community Public Notification Certification Form	
346	Community System Susceptibility Analysis Sheet	Community System Susceptibility Analysis Sheet	

347	Consumer Confidence Report Certification Form	Consumer Confidence Report Certification Form	
348	Discharge Monitoring Report for CBM Coal - Type 60 Effluent Example	Discharge Monitoring Report for CBM Coal - Type 60 Effluent (This form is not available in a Word or Excel Format)	C
349	Discharge Monitoring Report for CBM Coal - Type 60 Manual Example	Discharge Monitoring Report for CBM Coal - Type 60 Manual (This form is not available in a Word or Excel Format)	C
350	Discharge Monitoring Report for CBM Coal - Type 60 Standard Example	Discharge Monitoring Report for CBM Coal - Type 60 Standard (This form is not available in a Word or Excel Format)	C
351	Discharge Monitoring Report for Coal - Type 1 & Type 3 Example	Discharge Monitoring Report for Coal - Type 1 & Type 3 (This form is not available in a Word or Excel Format)	C
352	Discharge Monitoring Report for Coal - Type 11 Example	Discharge Monitoring Report for Coal - Type 11 (This form is not available in a Word or Excel Format)	C
353	Discharge Monitoring Report for Coal - Type 13 Example	Discharge Monitoring Report for Coal - Type 13 (This form is not available in a Word or Excel Format)	C
354	Discharge Monitoring Report for Coal - Type 14 Sand & Gravel Example	Discharge Monitoring Report for Coal - Type 14 Sand & Gravel (This form is not available in a Word or Excel Format)	C
355	Discharge Monitoring Report for Coal - Type 14 Fire Clay Example	Discharge Monitoring Report for Coal - Type 14 Fire Clay (This form is not available in a Word or Excel Format)	C

356	Discharge Monitoring Report for Coal - Type 14 Shale - Common Clay Example	Discharge Monitoring Report for Coal - Type 14 Shale - Common Clay (This form is not available in a Word or Excel Format)	C
357	Discharge Monitoring Report for Coal - Type 15 Example	Discharge Monitoring Report for Coal - Type 15 (This form is not available in a Word or Excel Format)	C
358	Discharge Monitoring Report for Coal - Type 38 Example	Discharge Monitoring Report for Coal - Type 38 (This form is not available in a Word or Excel Format)	C
359	Discharge Monitoring Report for Coal - Type 5 & Type 7 Example	Discharge Monitoring Report for Coal - Type 5 & Type 7 (This form is not available in a Word or Excel Format)	C
360	Discharge Monitoring Report for Coal - Type 9 Example	Discharge Monitoring Report for Coal - Type 9 (This form is not available in a Word or Excel Format)	C
361	Discharge Monitoring Report for NonCoal - Type 30 Example	Discharge Monitoring Report for NonCoal - Type 30 (This form is not available in a Word or Excel Format)	C
362	Discharge Monitoring Report for NonCoal - Type 32 Example	Discharge Monitoring Report for NonCoal - Type 32 (This form is not available in a Word or Excel Format)	C
363	Discharge Monitoring Report for NonCoal - Type 34 Example	Discharge Monitoring Report for NonCoal - Type 34 (This form is not available in a Word or Excel Format)	C
364	Discharge Monitoring Report for	Discharge Monitoring Report for	

	NonCoal - Type 36 & Type 48 & Type 50 Example	NonCoal - Type 36 & Type 48 & Type 50 (This form is not available in a Word or Excel Format)	C
365	Discharge Monitoring Report for NonCoal - Type 41 Example	Discharge Monitoring Report for NonCoal - Type 41 (This form is not available in a Word or Excel Format)	C
366	Discharge Monitoring Report for NonCoal - Type 42 Example	Discharge Monitoring Report for NonCoal - Type 42 (This form is not available in a Word or Excel Format)	C
367	Discharge Monitoring Report for NonCoal - Type 44 & Type 45 Example	Discharge Monitoring Report for NonCoal - Type 44 & Type 45 (This form is not available in a Word or Excel Format) Example	C
368	Discharge Monitoring Report for NonCoal - Type 46 Example	Discharge Monitoring Report for NonCoal - Type 46 (This form is not available in a Word or Excel Format) Example	C
369	Drinking Water State Revolving Fund (DWSRF) Loan Application Form	Drinking Water State Revolving Fund (DWSRF) Loan Application Form	
370	Drinking Water State Revolving Fund (DWSRF) Preapplication Form	Drinking Water State Revolving Fund (DWSRF) Preapplication Form	
371	Drinking Water State Revolving Fund (DWSRF) Supplemental General Conditions	Drinking Water State Revolving Fund (DWSRF) Supplemental General Conditions (This form is not available in a Word or Excel Format)	
372	Emissions Statement Reporting Form	Emissions Statement Reporting Form	

373	Excess Emission Monitoring Report	Excess Emission Monitoring Report	
374	Exemption Claim Form for Cofired Combustors (Appendix H - Division 3)	Exemption Claim Form for Cofired Combustors (Appendix H - Division 3)	
375	Exemption Claim Form For Incinerators Burning Only Pathological, Low-Level Radioactive, and Chemotherapeutic Waste (Appendix H - Division 3)	Exemption Claim Form For Incinerators Burning Only Pathological, Low-Level Radioactive, and Chemotherapeutic Waste (Appendix H - Division 3)	
376	Field Operation Division NPDES Individual Permit Application Addendum Form	Field Operation Division NPDES Individual Permit Application Addendum Form	C
377	Field Operation Division NPDES Individual Permit Application Minor Permit Modification Addendum Form	Field Operation Division NPDES Individual Permit Application Minor Permit Modification Addendum Form	C
378	Gasoline Dispensing Facility Information Survey	Gasoline Dispensing Facility Information Survey	
379	General Permit Application Form - NOI-61 & 49 This form is replaced by Form # 498	General Permit Application Form - NOI-61 & 49 This form is replaced by Form # 498	C
380	General Permit Application Package - NOI-11	General Permit Application Package - NOI-11	
381	General Permit Application Package - NOI-12	General Permit Application Package - NOI-12	
382	General Permit Application Package - NOI-14	General Permit Application Package - NOI-14	
383	General Permit Application Package - NOI-15	General Permit Application Package - NOI-15	
384	General Permit Application Package - NOI-16	General Permit Application Package - NOI-16	
385	General Permit Application Package - NOI-17	General Permit Application Package - NOI-17	
386	General Permit Application Package - NOI-18	General Permit Application Package - NOI-18	
387	General Permit Application Package - NOI-2	General Permit Application Package - NOI-2	

388	General Permit Application Package - NOI-20	General Permit Application Package - NOI-20	
389	General Permit Application Package - NOI-23	General Permit Application Package - NOI-23	
390	General Permit Application Package - NOI-24	General Permit Application Package - NOI-24	
391	General Permit Application Package - NOI-25	General Permit Application Package - NOI-25	
392	General Permit Application Package - NOI-28	General Permit Application Package - NOI-28	
393	General Permit Application Package - NOI-3	General Permit Application Package - NOI-3	
394	General Permit Application Package - NOI-34	General Permit Application Package - NOI-34	
395	General Permit Application Package - NOI-36	General Permit Application Package - NOI-36	
396	General Permit Application Package - NOI-6	General Permit Application Package - NOI-6	
397	General Permit Application Package - NOI-67	General Permit Application Package - NOI-67	
398	General Permit Renewal Form	General Permit Renewal Form	
399	Hydrograph Control Release (HCR) Attachment	Hydrograph Control Release (HCR) Attachment	
400	Impressed Current Cathodic Protection System 60-Day Inspection Log	Impressed Current Cathodic Protection System 60-Day Inspection Log	
401	Individual NPDES Permit Noncompliance Notification (5-day Report)	Individual NPDES Permit Noncompliance Notification (5-day Report)	C
403	Interior Lining Inspection Form	Interior Lining Inspection Form	
404	Interior Lining Report Form	Interior Lining Report Form	
405	Lead and Copper Monitoring Data Report	Lead and Copper Monitoring Data Report	
406	Manual Interstitial Monitoring Monthly Log	Manual Interstitial Monitoring Monthly Log	
407	Material Safety Data Sheet Reporting	Material Safety Data Sheet Reporting	C
408	Maximum Residual Disinfectant	Maximum Residual Disinfectant	

	Level Input Form (Samples)	Level Input Form (Samples)	
409	Maximum Residual Disinfectant Level Input Form (Sources)	Maximum Residual Disinfectant Level Input Form (Sources)	
410	Medical Waste Notification Form	Medical Waste Notification Form	
411	Medical Waste Transporter Permit Application	Medical Waste Transporter Permit Application	
412	Medical Waste Treatment Permit Application	Medical Waste Treatment Permit Application	
414	Monthly Statistical Inventory Reconciliation (SIR) Report	Monthly Statistical Inventory Reconciliation (SIR) Report	
415	Municipal POTW SSO/MS4 Event Reporting Form	Municipal POTW SSO/MS4 Event Reporting Form	
416	Municipal Water Pollution Prevention (MWPP) Annual Report (Collection Systems) Package	Municipal Water Pollution Prevention (MWPP) Annual Report (Collection Systems) Package	
417	Municipal Water Pollution Prevention (MWPP) Annual Report Package	Municipal Water Pollution Prevention (MWPP) Annual Report Package	
418	Municipal Water Pollution Prevention Resolution Form	Municipal Water Pollution Prevention Resolution Form	
419	MWPP Sewage Sludge Survey	MWPP Sewage Sludge Survey	
420	Non-Community Public Notification Certification Form	Non-Community Public Notification Certification Form	
421	Non-Compliance Report Form	Non-Compliance Report Form	
422	Notice of Intent to Permanently Close Underground Storage Tanks	Notice of Intent to Permanently Close Underground Storage Tanks	
423	Notice of Proposed UST New Installation or Upgrade	Notice of Proposed UST New Installation or Upgrade	
424	Notification - Above the Threshold Planning Quantities (TPQ) of Extremely Hazardous Substances	Notification - Above the Threshold Planning Quantities (TPQ) of Extremely Hazardous Substances	C
425	Notification of Election of Coverage under The Alabama Drycleaning Environmental Response Trust Fund Act	Notification of Election of Coverage under The Alabama Drycleaning Environmental Response Trust Fund Act	
426	Nox Budget Permit Application	Nox Budget Permit Application	

	Form	Form	
427	Nox Budget Retired Unit Exemption Claim Form	Nox Budget Retired Unit Exemption Claim Form	
429	NPDES Annual Notice of Registration (NOR) This form is for CAFO Registration	NPDES Annual Notice of Registration (NOR) This form is for CAFO Registration	C
430	NPDES Discharge Monitoring Report Form (Monthly)	NPDES Discharge Monitoring Report Form (Monthly)	
431	NPDES Discharge Monitoring Report Form (Quarterly)	NPDES Discharge Monitoring Report Form (Quarterly)	
432	NPDES Individual Permit Pollution Abatement / Treatment Measures and Sediment Control Structures Certification Report	NPDES Individual Permit Pollution Abatement / Treatment Measures and Sediment Control Structures Certification Report	C
433	NPDES Permitted Coalbed Methane Operations Pollution Abatement/Treatment Measures and Waste Treatment Facilities Certification Report	NPDES Permitted Coalbed Methane Operations Pollution Abatement/Treatment Measures and Waste Treatment Facilities Certification Report	C
434	Open Burning Incident Report	Open Burning Incident Report	
435	Operator Certification Renewal Form (This form is not available in a Word Format)	Operator Certification Renewal Form	
436	Perc Dry Cleaner Status Update	Perc Dry Cleaner Status Update	
437	Permit Application for Compliance Schedule	Permit Application for Compliance Schedule	
438	Permit Application for Continuous Emission Monitoring Systems (CEMS)	Permit Application for Continuous Emission Monitoring Systems (CEMS)	
439	Permit Application Solid Waste Disposal Facility	Permit Application Solid Waste Disposal Facility	
440	Petroleum Solvent Dry Cleaning Questionnaire	Petroleum Solvent Dry Cleaning Questionnaire	
441	Plant and Collection System Personnel Inventory	Plant and Collection System Personnel Inventory	
442	Potable Water Laboratory Certification Application	Potable Water Laboratory Certification Application	

443	Progress Report Form	Progress Report Form	
444	Project Completion Form	Project Completion Form	
445	PSD Project Information Form	PSD Project Information Form	
446	Raw Sewage Bypass and Overflow Event Reporting Form	Raw Sewage Bypass and Overflow Event Reporting Form	
447	Release Information Form	Release Information Form	C
448	Remediation Approval Form	Remediation Approval Form	
449	Remediation Reporting Form	Remediation Reporting Form	
450	Representative Stormwater Outfall Certification	Representative Stormwater Outfall Certification	
451	Request for Coal Permit Post-Mining Discharge Limitations	Request for Coal Permit Post-Mining Discharge Limitations	C
452	Request for Release from Monitoring and Reporting Requirements	Request for Release from Monitoring and Reporting Requirements	C
453	Request to Remove Subsurface Withdrawal From Discharge Structure	Request to Remove Subsurface Withdrawal From Discharge Structure	C
454	Request to Remove Treatment Basin/Pond or Other Discharge Structure	Request to Remove Treatment Basin/Pond or Other Discharge Structure	C
455	Required Information for Mixing Zone Modeling	Required Information for Mixing Zone Modeling	
456	Segmental Water System Certification Application	Segmental Water System Certification Application	
457	SID Discharge Monitoring Report Form (Monthly)	SID Discharge Monitoring Report Form (Monthly)	
458	SID Discharge Monitoring Report Form (Quarterly)	SID Discharge Monitoring Report Form (Quarterly)	
459	SRF Payment Request Form	SRF Payment Request Form (This form is not available in a Word or Excel Format)	
460	Statistical Inventory Reconciliation SIR 7 Day Release Investigation Notice Form	Statistical Inventory Reconciliation SIR 7 Day Release Investigation Notice Form	
461	Surface Source Susceptibility Analysis Worksheet	Surface Source Susceptibility Analysis Worksheet	

462	Tank Trust Fund Eligibility / Ineligibility Determination Form	Tank Trust Fund Eligibility / Ineligibility Determination Form
464	Toxicity Discharge Monitoring Report Form	Toxicity Discharge Monitoring Report Form
465	Toxicity Test Report Summary	Toxicity Test Report Summary
466	Transfer Agreement Form	Transfer Agreement Form
467	UIC Permit Application Existing Discharge	UIC Permit Application Existing Discharge
468	UIC Permit Application New Discharge	UIC Permit Application New Discharge
469	Underground and Above Ground Storage Tank Transfer of Ownership	Underground and Above Ground Storage Tank Transfer of Ownership
471	UST ARBCA Tier 1 Report Forms	UST ARBCA Tier 1 Report Forms (This form is available for purchase)
472	UST ARBCA Tier 2 Report Forms	UST ARBCA Tier 2 Report Forms (This form is available for purchase)
473	UST ARBCA Tier 3 Report Forms	UST ARBCA Tier 3 Report Forms (This form is available for purchase)
474	UST Closure Site Assessment Report Form	UST Closure Site Assessment Report Form
475	UST Free Product Recovery Report Form	UST Free Product Recovery Report Form
476	UST Groundwater Monitoring Report Form	UST Groundwater Monitoring Report Form
477	UST Line Tightness Test Report Form	UST Line Tightness Test Report Form
478	UST Natural Attenuation Monitoring Report Form	UST Natural Attenuation Monitoring Report Form
479	UST Release Fact Sheet	UST Release Fact Sheet
480	UST Release Report Form	UST Release Report Form
481	UST Site Classification System Checklist	UST Site Classification System Checklist
482	UST System Effectiveness Monitoring Report Form	UST System Effectiveness Monitoring Report Form
483	UST Tracer Tank Tightness Test Report Form	UST Tracer Tank Tightness Test Report Form

484	UST Ullage Tank Tightness Test Report Form	UST Ullage Tank Tightness Test Report Form	
485	UST Vacuum Tank Tightness Test Report Form	UST Vacuum Tank Tightness Test Report Form	
486	UST Volumetric Overfill Tank Tightness Test Report Form	UST Volumetric Overfill Tank Tightness Test Report Form	
487	UST Volumetric Underfill Tank Tightness Test Report Form	UST Volumetric Underfill Tank Tightness Test Report Form	
488	Water Supply Construction Permit Application	Water Supply Construction Permit Application	
489	Water Supply Permit Application (Modification)	Water Supply Permit Application (Modification)	
490	Water Supply Permit Application (Renewal)	Water Supply Permit Application (Renewal)	
491	Water System Update	Water System Update	
492	UST Closure Total Potential Voc Emissions Calculations	UST Closure Total Potential Voc Emissions Calculations	
493	112 (j) Part 1 Applicability Notification	112 (j) Part 1 Applicability Notification	
494	Birmingham Fuel Supplier Report	Birmingham Fuel Supplier Report	
495	Major Source Operating Permit Skeleton Form	Major Source Operating Permit Skeleton Form	
496	Notice of Demolition and/or Asbestos Removal	Notice of Demolition and/or Asbestos Removal	
497	Asbestos Removal Contractor Certification	Asbestos Removal Contractor Certification	
498	NPDES Construction, Noncoal/Nonmetallic Mining and Dry Procession Less than Five Acres, Other Land Disturbance Activities Application Form	NPDES Construction, Noncoal/Nonmetallic Mining and Dry Procession Less than Five Acres, Other Land Disturbance Activities Application Form	C
499	NPDES Construction, Noncoal Mining Less than Five Acres Stormwater Registration Termination Request and Certification Form	NPDES Construction, Noncoal Mining Less than Five Acres Stormwater Registration Termination Request and Certification Form	C
500	NPDES Construction, and Noncoal Mining Less than Five Acres Stormwater Inspection Report and	NPDES Construction, and Noncoal Mining Less than Five Acres Stormwater Inspection Report and	C

	BMP Certification Form	BMP Certification Form	
501	NPDES Construction, and Noncoal Mining Less than Five Acres Stormwater Noncompliance Notification Report Form	NPDES Construction, and Noncoal Mining Less than Five Acres Stormwater Noncompliance Notification Report Form	C
502	Visible Emission Field Test Sheet	Visible Emission Field Test Sheet **Only available in PDF**	
503	General Permit for Phase II Small Municipal Separate Storm Sewer Systems (MS4) ALNOI	General Permit for Phase II Small Municipal Separate Storm Sewer Systems (MS4) ALNOI	
505	Water and Wastewater Operator Exam Application	Water and Wastewater Operator Exam Application **Only available in PDF**	C
506	Water and Wastewater Operator Experience Verification	Water and Wastewater Operator Experience Verification **Only available in PDF**	C
507	Water and Wastewater Reciprocal Application	Water and Wastewater Reciprocal Application **Only available in PDF**	C
508	Water and Wastewater Operator for Multiple Systems	Water and Wastewater Operator for Multiple Systems **Only available in PDF**	C
510	Cooling Water Supplemental Information	Cooling Water Supplemental Information	
511	EDMR1 Permittee Registration Form	EDMR1 Permittee Registration Form	
512	EDMR2 Electronic Signature Application Agreement	EDMR2 Electronic Signature Application Agreement	
513	EDMR3 Deactivation Request	EDMR3 Deactivation Request Form	

	Form	
514	Daily Discharge Monitor Report	Daily Discharge Monitor Report **Only available in PDF**
515	Monthly Discharge Monitoring Report	Monthly Discharge Monitoring Report **Only available in PDF**
516	Supplemental Petroleum Application Information	Supplemental Petroleum Application Information
530	Technical Proposal for Qualification as a Scrap Tire Fund Remediation Center	Technical Proposal for Qualification as a Scrap Tire Fund Remediation Center
531	Hydrogeology Unit Evaluation Report Form	Hydrogeology Unit Evaluation Report Form
532	UIC Permit Application for Coal Mining Wastewater	UIC Permit Application for Coal Mining Wastewater
533	Documentation of Disability Related Needs	Documentation of Disability Related Needs
534	EHS Notification Form	EHS Notification Form
535	CT Profiling Spreadsheet	CT Profiling Spreadsheet
536	Scrap Tire Manifest	Scrap Tire Manifest
537	Scrap Tire Registration &	Scrap Tire Registration & Exemption

	Exemption Application	Application
538	Scrap Tire Transporter Permit Application	Scrap Tire Transporter Permit Application
539	Scrap Tire Quarterly Report	Scrap Tire Quarterly Report
540	Scrap Tire Processor Permit Application	Scrap Tire Processor Permit Application
541	Scrap Tire Site Registration	Scrap Tire Site Registration
542	Brownsfield State Revolving Fund PreApplication Form	Brownsfield State Revolving Fund PreApplication Form
543	Brownsfield State Revolving Fund Application Fund	Brownsfield State Revolving Fund Application Fund
545	Cathodic Protection Monitoring for Galvanic Systems	Cathodic Protection Monitoring for Galvanic Systems
546	Alabama Hazardous Waste Receipt for Samples and Documents	Alabama Hazardous Waste Receipt for Samples and Documents
547	Water Treatment Plant Quarterly Report for the Disinfectants and Disinfection Byproducts Rule	Water Treatment Plant Quarterly Report for the Disinfectants and Disinfection Byproducts Rule
548	Pollution Prevention Survey	Pollution Prevention Survey
549	NPDES Coalbed Methane	NPDES Coalbed Methane Operation

	Operation	
550	Brownfields Assessment Request Application	Brownfields Assessment Request Application
551	ADEM Line Leak Detector (LLD) Test Report Form	ADEM Line Leak Detector (LLD) Test Report Form
8700-12	Notification of Regulated Waste Activity	Notification of Regulated Waste Activity

Scrap Tire Forms

Send mail to webmaster@adem.state.al.us with questions or comments about this web site.
Last modified: 07/27/07

APPLICATION FOR APPROVAL OF ALTERNATIVE TREATMENT TECHNOLOGIES

Please complete all items below. Mark N/A for any that are not applicable. Include any support data that may be applicable. Use additional paper if necessary with a reference to the appropriate section and number(s).

=== === === === === === === === === === === === === ===

A. *GENERAL*

A1. Is the treatment technology best suited for on-site use at the point of generation, or is it adaptable for use as a commercial or regional treatment process receiving medical waste from several generators?

On-site _____ Commercial/Regional _____ Both _____

A2. Is this treatment technology specified for use at small generator facilities (those that treat less than 220 pounds per month)?

Yes _____ No _____

A3. Has this treatment technology been approved/disapproved in any other state? If so, please indicate which states have issued a decision and submit copies of approvals/disapprovals.

A4. Has the use of this equipment ever resulted in any injuries of any kind, or the transmission of any disease to any person? Describe all such instances.

A5. Has the use of this equipment ever resulted in any environmental or occupational safety violation (federal, state, or local)? Describe all such instances.

A6. Have you reviewed all applicable state solid and medical waste regulations for medical waste management and disposal?

Yes _____ No _____

A7. Have you inquired as to whether any other permits are required? Please enclose agency response and requirements with your application. List all required permits and enclose copies of any permit approvals.

Yes _____ No _____ NOTE: Local governments or other agencies may require permits and/or approvals.

B. *LEVEL OF TREATMENT*

B1. Does the level of microbial inactivation achieved by the treatment process meet the following definition?
"Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log10 Reduction or greater; and inactivation of B. stearothermophilus spores or B. subtilis spores at a 4 Log10 reduction or greater."

Yes _____ No _____ If no, specify where the definition is unfulfilled.

C. *CHARACTERIZATION OF PROPOSED TREATMENT PROCESS*

C1. Please check the appropriate categories that best describe the methods used by this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

Chemical	____	Grinder	____
Encapsulation	____	Heat	____
Microwave	____	Irradiation	____
Plasma Arc	____	Mechanical	____
Steam	____	Radiowave	____
Other (specify)	_____		

D. *WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS*

	Type of Waste	Compatible	Non-compatible
D1.	Animal Waste	_____	_____
D2.	Blood & Body Fluids	_____	_____
D3.	Microbiological Waste	_____	_____
D4.	Pathological Waste	_____	_____
D5.	Renal Dialysis Waste	_____	_____

D6. Sharps _____ _____

D7. Surgical Waste _____ _____
Please refer to the state medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D8. What waste characteristics present the greatest challenge to the proposed treatment process.

Organic materials ____ Liquids ____

Density/Compaction ____ Other characteristics ____ Specify: ____

_____

D9. Describe by composition (i.e., material and percentage) those medical wastes that would pose the most challenge to the proposed technology. Why?

D10. Describe the physical or chemical components of medical wastes that would interfere, cause mechanical breakdown, or compromise the treatment process or microbial inactivation efficacy.

=== === === === === === === === === === === === === === ===

E. *MICROBIOLOGICAL TEST PROCEDURES*

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeast, parasites, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log_{10} Reduction or greater. Bacterial spores shall be inactivated at a 4 Log_{10} Reduction or greater. A representative from each of the microbial groups, listed in "E1" below, are required to be tested.

E1. Listed below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. If there are any data that supports or refutes the inactivation of any of the biological indicators using the proposed treatment process under normal operating conditions, please check the appropriate space next to the indicator.

NOTE: *If protocols utilized by the applicant to generate microbial inactivation data are deemed unacceptable by the Department, the Department reserves the right to request that the applicant resubmit data generated from Department-approved protocols. If data has not yet been procured to support the inactivation of the listed biological indicators below, please contact the Department before initiating efficacy testing to ensure research protocols are in accordance with the Department's requirements.*

Vegetative Bacteria:

Staphylococcus aureus (ATCC 6538) _____

Pseudomonas aeruginosa (ATCC 15442) _____

Fungi:

Candida albicans (ATCC 18804) _____

Penicillium chrysogenum (ATCC 24791) _____

Aspergillus niger _____

Viruses:

Polio 2 or Polio 3 _____

MS-2 Bacteriophage (ATCC 15597-B1) _____

Parasites:

Cryptosporidium spp. Oocysts _____

Giardia spp. Cysts _____

Mycobacteria:

Mycobacterium terrae _____

Mycobacterium phlei _____

Mycobacterium bovis (BCG) (ATCC 35743) _____

Bacterial Spores:

B. stearothemophilus (ATCC 7953) _____

B. subtilis (ATCC 19659) _____

E2. Were the results certified by an independent public health or certified testing laboratory?

Yes* _____ No _____

** If yes, indicate the name, address, and telephone number of the certifying laboratory and attach the test protocol, results and an explanation of any available data not supporting the reduction factors referenced above.*

F. *BY-PRODUCTS AND DISCHARGES OF THE TREATMENT PROCESS*

F1. Please indicate all by-products and discharges (to air, water, or land) which may be generated as a result of this alternative treatment technology.

Aerosols	____	Leachate	____	Stack Emissions	____
Ash	____	Liquid	____	Steam	____
Chemical Residues	____	Odor	____	Vapors or Fumes	____
Dust	____	Slag	____	_____	____
Heat	____	Smoke	____	_____	____

F2. If any of the above by-products or discharges are indicated, how will they be controlled?

F3. If there are no by-products or discharges indicated, how was this determined?

F4. Are any of these by-products or discharges ADEM-listed hazardous wastes (ADEM Administrative Code 335-14)? If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

Yes _____ No _____

G. *ENVIRONMENTAL EFFECTS OF THE TREATMENT PROCESS*

G1. Are any negative effects on the environment anticipated from the use of the treatment process and/or disposal of the treated waste from the treatment process?

Yes _____ No _____

G2. What environmental, occupational, and/or public health hazards would be associated with a malfunction of the treatment process? Specify _____

_____

G3. If the treatment process includes the use of water, steam, or other liquids, how will this waste discharge be handled (i.e., sewer, recycled, etc.)? Specify _____

G4. What are the physical characteristics of the waste residues generated from the treatment process (i.e., wet, dry, shredded, powdered, etc.)? Specify _____

_____

G5. How will the treated medical waste from this process be disposed of (i.e., landfill, incineration, recycled, etc.)? Specify _____

G6. Are any by-products classified as hazardous waste according to Division 335-14 of the ADEM Administrative Code? Yes _____ No _____

H. *OCCUPATIONAL HAZARDS*

H1. What training will the operator(s) of the treatment process receive? _____

H2. What frequency will update training be provided? _____

I. *CRITICAL FACTORS OF THE TREATMENT PROCESS*

I1. What are the critical factors that influence the specific treatment technology? Specify

I2. What are the consequences if these factors are not met? Specify _____

I3. What type of ongoing maintenance is required in the operation of the treatment system? Specify (may attach maintenance manual) _____

I4. What emergency measures would be required in the event of a malfunction? Specify _____

I5. What is the maximum amount of waste to be treated by this process per cycle or per hour? _____pounds

I6. How long is a cycle? _____minutes

J. *CHEMICAL INACTIVATION TREATMENT PROCESSES*

Complete this section if the treatment process involves the use of chemical inactivation.

J1. What is the name of the active ingredient? _____

J2. What concentrations must be used and maintained? _____

J3. At what pH is the chemical agent active? _____

J4. What is the minimum contact time? _____ minutes

J5. Specify any incompatibility with specific materials and surfaces. _____

_____

J6. What is the pH of any end products (i.e., liquid effluents)? _____

J7. List any additional factors that may interfere with the chemical's inactivation potential.

_____

_____

J8. What is the active life of the chemical agent after it has been exposed to air or medical waste?

_____

J9. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use? If yes, please attach a copy of the study and test results. _____

J10. Is a MSDS attached? Yes_____ No_____

J11. Is the chemical agent registered for this specific use with the USEPA Pesticide Registration Division? Yes_____ No_____ If yes, provide number _____

J12. Is the spent chemical agent classified as a hazardous waste by Division 335-14 of the ADEM Administrative Code? Yes_____ No_____

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K. *QUALITY ASSURANCE AND VERIFIVATION OF MICROBIAL INACTIVATION*

K1. Specify how quality assurance of the treatment process is addressed. _____

_____

K2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system? _____

K3. Other than the biological indicators listed in Section E, what other indicators, integrators, or monitoring devices would be used to show that the treatment unit or process was functioning properly? _____

_____

_____

K4. How is it determined that the processed waste has received proper treatment?

Temperature indicator:	Visual only___	Continuous___	Both___
Pressure indicator:	Visual only___	Continuous___	Both___
Time indicator:	Visual only___	Continuous___	Both___
Chemical concentration indicator:	Visual only___	Continuous___	Both___

Other: Please specify _____

K5. How have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process? _____

_____

K6. What is the established procedure and frequency to calibrate the process monitors (gauges, clocks, computers, etc.)? _____

K7. How are the process monitors interfaced with the system's operations to effect proper treatment conditions? _____

_____

K8. How are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately affected? _____

_____

K9. What failure mode and effect analyses have been performed on the treatment system?

_____

_____

L. *OTHER RELEVANT INFORMATION AND COMMENTS*

All approvals or denials received from other states, counties or agencies concerning any aspect of equipment operation and efficacy; as well as all safety, competency or training requirements for the users/operators, etc. must also be included.

CERTIFICATION STATEMENT

I certify that the information requested and contained in this document is accurate and complete and that all existing documentation requested in this application for this system or similar systems is provided. The Vendor, identified below, agrees to provide ADEM all results of all studies conducted by or for any state, company, agency, country, or any other person as defined by Division 335-13 of the ADEM Administrative Code, which the vendor conducts, or is in any way aware of, to determine the operational performance of any aspect of the equipment for which authorization to operate in this state is requested on the filing of this application. I am aware that regulated medical waste management systems to be operated in this state for regulated medical waste treatment and/or destruction must be identical to the system described in this application for authorization to operate in this state and for which operational data is presented in the application for ADEM's review. Any and all changes in the system and related equipment after this application submittal and ADEM's review and authorization to operate must be submitted in writing to ADEM prior to use. The ADEM permitting conditions or other agency's authorizations granted to operate this system to treat and/or destroy regulated medical waste will be reviewed by ADEM periodically to ensure specifically authorized regulated medical waste technology systems meet currently accepted standards for regulated medical waste management. ADEM may modify system operational or performance requirements for systems that receive prior authorizations to operate, if warranted to protect human health and the environment.

I am further aware that on reviewing the completed application and the required attachments, ADEM may have additional questions and require submissions of data and other information deemed necessary regarding this or related medical waste disposal systems. Failure to provide all existing requested information will result in delays in processing the request for authorization to operate. Failure to provide all required information as outlined in this application, or willfully withholding information, may be cause for ADEM to deny or rescind authorization to operate if ADEM determines that the information not submitted would have been in any way relevant to its review of this technology.

Name of system or equipment	Model Number
Name of certifying person (must be a owner, partner, etc.)	Title
Signature of certifying person	Date
Name of Vendor (company)	Telephone
Mailing Address	Fax Number
City, State & Zip Code	E-mail address
Vendor's contact person	Telephone

IW-20
Rev. 8/04

West Virginia Department of Health and Human Resources
Office of Environmental Health Services
Infectious Medical Waste Program

Application for Alternative Treatment Technology Evaluation and Approval

Complete the following application and return it along with all supporting data which maybe applicable and the evaluation fee of $500.00. Checks should be made payable to the WV Bureau for Public Health. Use additional paper if necessary, reference with the related section and number(s).

A. GENERAL

A1. Is the treatment technology best suited for on-site use at the point of generation, or is it adaptable for use as a commercial or regional treatment process receiving waste from several generators?
On-site _____ Commercial/Regional _____ Both _____

A2. Is this treatment technology specified for use at small generator facilities such as physician, dental, or veterinary offices or clinics?
Yes _____ No _____

A3. Has this treatment technology been approved/disapproved in any other state? If so, please indicate which states have issued a decision and submit copies of approvals/disapprovals.
Yes _____ No _____

A4. Has the use of this equipment ever resulted in any environmental or occupational safety violation (federal, state, or local)?
Yes _____ No _____

A5. Has the use of this equipment ever resulted in any injuries, of any kind, or transmissions of any disease to any person? Describe all such instances.
Yes _____ No _____

A6. Have you reviewed all applicable state solid and medical waste regulations for medical waste acceptance, treatment, and disposal?
Yes _____ No _____

A7. Have you inquired as to whether any other permits are required? Please enclose agency response and requirements with your application. List all required permits and enclose copies of any permit approvals.
Yes _____ No _____

B. LEVEL OF TREATMENT

B1. Does the level of microbial inactivation achieved by the treatment process meet the following definition?

"Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of Bacillus stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater."

Yes _____ No _____ If no, specify where the definition is unfulfilled.

C. CHARACTERIZATION OF PROPOSED TREATMENT PROCESS

C1. Please check the appropriate categories that best describe the methods of this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

Chemical	_____	Mechanical	_____
Encapsulation	_____	Microwave	_____
Grinder	_____	Plasma Arc	_____
Hammer mill	_____	Radiowave	_____
Heat	_____	Shredder	_____
Irradiation	_____	Other (specify)	_____

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

Please identify if the proposed system is compatible or non-compatible with the following types of waste.

	Type of Waste	Compatible	Non-compatible
D1.	Cultures and stocks of infectious agents and associated biologicals	_____	_____
D2.	Liquid human and animal waste including blood and blood products and body fluids	_____	_____
D3.	Pathological waste	_____	_____
D4.	Contaminated waste from animals	_____	_____
D5.	Sharps	_____	_____
D6.	Other _____	_____	_____

Please refer to the state medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D7. What waste characteristics present the most challenge to the proposed treatment process:

Organic materials _____
Liquids _____
Density/compaction _____
Other characteristics _____ Specify: _____

D8. Describe by composition (i.e., material and percentage) those medical wastes that would pose the most challenge to the proposed technology. Why?

D9. Describe the physical or chemical components of medical wastes that would interfere, cause mechanical breakdown, or compromise the treatment process or microbial inactivation efficacy.

E. MICROBIOLOGICAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log reduction or greater. Bacterial spores shall be inactivated at a 4 Log reduction or greater. A representative from each of the following microbial groups is required for testing.

E1. Listed below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. If there are any data either to support or refute the inactivation of any of the biological indicators using the proposed treatment process under normal operating conditions, please check the appropriate space next to the indicator.

NOTE: If protocols utilized by the applicant to generate microbial inactivation data are deemed unacceptable by the Department, the Department reserves the right to request that the applicant resubmit data generated from Department-approved protocols. If data has not yet been procured to support the inactivation of the listed biological indicators below, please contact the Department before initiating efficacy testing to ensure research protocols are in accordance with the Department's requirements.

Vegetative Bacteria
- Staphylococcus aureus (ATCC 6538) _____
- Pseudomonas aeruginosa (ATCC 15442) _____

Fungi
- Candida albicans (ATCC 18804) _____
- Penicillium chrysogenum (ATCC 24791) _____
- Aspergillus niger _____

Viruses
- Polio 2 or Polio 3 _____
- MS-2 Bacteriophage (ATCC 15597-B1) _____

Parasites
- Cryptosporidium spp. oocysts _____
- Giardia spp. cysts _____

Mycobacteria
- Mycobacterium terrae _____
- Mycobacterium phlei _____
- Mycobacterium bovis (BCG) ATCC 35743) _____

Bacterial Spores
- B stearothermophilus (ATCC 7953) _____
- B. subtilis (ATCC 19659) _____

E2. Were the results certified by an independent public health or certified testing laboratory?
Yes _____ No _____

If yes, indicate the name, address, and telephone number of the certifying laboratory and attach the test protocol, results and an explanation of any available data not supporting the reduction factors referenced above.

F. BY-PRODUCTS AND DISCHARGES OF THE TREATMENT PROCESS

F1. Please indicate all by-products and discharges (to air, water, or land) which may be generated as a result of this alternative treatment technology.

Aerosols _____	Leachate _____	Smoke _____
Ash _____	Liquid _____	Stack Emissions _____
Chemical Residues _____	Odor _____	Steam _____
Dust _____	Slag _____	Vapors or Fumes _____
Heat _____	Other, specify _____	

F2. If any of the above by-products or discharges are indicated, how will they be controlled?

F3. If there are no by-products or discharges indicated, how was this determined?

F4. Are any of these by-products or discharges USEPA-listed hazardous wastes (40 CFR Part 261), biohazardous, etc.?
Yes _____ No _____

If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

G. ENVIRONMENTAL EFFECTS OF THE TREATMENT PROCESS

G1. Are any negative effects on the environment anticipated from the use of the treatment process and/or disposal of the treated waste from the treatment process?

G2. What environmental, occupational, and/or public health hazards would be associated with a malfunction of the treatment process? Specify.

G3. If the treatment process includes the use of water, steam, or other liquids, how will this waste discharge be handled (i.e., sewer, recycled, etc.)? Specify.

G4. What are the physical characteristics of the waste residues generated from the treatment process (i.e., wet, dry, shredded, powdered, etc.)? Specify.

G5. How will the treated medical waste from this process be disposed of (i.e., landfill, incineration, recycled, etc.)? Specify.

G6. Are any by-products classified as hazardous waste (40 CFR Part 261)?
Yes _____ No _____ Complete Item A6.

H. OCCUPATIONAL HAZARDS

H1. What are the potential hazards associated with the treatment process?

H2. What hazard abatement/reduction strategies will be used during the operation of this treatment process (include engineering controls, person protection equipment, etc.)?

H3. What training will the operator(s) of the treatment process receive?

I. CRITICAL FACTORS OF THE TREATMENT PROCESS

I1. What are the critical factors that influence the specific treatment technology? Specify.

I2. What are the consequences if these factors are not met? Specify.

I3. Explain the ease and/or difficulty of operation of the medical waste treatment system. Specify.

I4. What type of ongoing maintenance is required in the operation of the treatment system? Specify.
Maintenance Manual Attached? Yes _____ No _____

I5. What emergency measures would be required in the event of a malfunction? Specify.

I6. How are these measures addressed in an emergency plan or in the operations protocol?

I7. What is the maximum amount of waste to be treated by this process per cycle?

I8. How long is a cycle?

J. CHEMICAL TREATMENT PROCESS

J1. If the treatment process involves the use of chemical inactivation:

a. What is the name of the active ingredient?

b. What concentrations must be used and maintained?

c. At what pH is the chemical agent active?

d. What is the necessary contact time?

e. If there is any incompatibility with specific materials and surfaces, specify.

f. What is the pH of any end products (i.e., liquid effluents)?

g. List any additional factors or circumstances that may interfere with the chemical's inactivation potential.

J2. What is the active life of the chemical agent after it has been exposed to air or contaminated medical waste?

J3. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use? If yes, please attach a copy of the study and test results.

J4. What health and safety hazards may be associated with the chemical (present and long-term)? Specify.
MSDS Attached? Yes _____ No _____

J5. Is the chemical agent registered for this specific use with the Environmental Protection Agency (USEPA) Pesticide Registration Division?
Yes _____ No _____
If yes, provide the USEPA registration number _____ and a copy of the EPA-approved label instructions for use.

J6. Is the spent chemical agent classified as a hazardous waste by USEPA (40 CFR Part 261) or by other state criteria?
Yes _____ No _____ If yes, specify whether by USEPA or by which state(s).

J7. Is an environmental impact study for the chemical agent available?
Yes _____ No _____ If yes, attach a copy of this information.

K. QUALITY ASSURANCE AND VERIFICATION OF MICROBIAL INACTIVATION

K1. How is the quality assurance of the treatment process addressed? Specify.

K2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system? Specify.

K3. Other than the biological indicators listed in Section E, what other indicators, integrators, or monitoring devices would be used to show that the treatment unit or process was functioning properly? (Please describe and explain.)

K4. How is it determined that the processed waste has received proper treatment? (Check the appropriate item.)

Temperature indicator:	visual only _____	continuous _____	both _____
Pressure indicator:	visual only _____	continuous _____	both _____
Tune indicator:	visual only _____	continuous _____	both _____
Chemical concentration indicator:	visual only _____	continuous _____	both _____

Other: Please specify _____

K5. How have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process? Specify.

K6. What is the established process monitor calibration schedule, and what is its frequency of calibration?

K7. How are the process monitors interfaced to the system's operations to effect proper treatment conditions? Explain.

K8. How are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately affected? Explain.

K9. What failure mode and effect analyses have been performed on the treatment system? Specify and provide.

L. POST-TREATMENT RESIDUE DISPOSAL, RECLAMATION OR RECYCLING

L1. How will the treated medical wastes from this process be disposed of:
Burial in an approved landfill _____ Incineration _____ Recycled _____

L2. If the wastes are to be recycled, provide additional evidence regarding this strategy.

L3. If the wastes arc to be recycled, what percentage of the treated waste will be recycled? How will the remainder of the treated waste be disposed of ?

M. POTENTIAL ENVIRONMENTAL BENEFITS

M1. Has an energy analysis been conducted on the proposed technology?
Yes _____ No _____ If yes, specify and provide results of that analysis.

M2. Has an economic analysis been performed on the proposed technology?
Yes _____ No _____ If yes, specify and provide results of that analysis.

M3. How does this treatment technology improve on existing medical waste treatment and disposal methods? Specify.

M4. What is the potential of this proposed technology for waste volume reduction? Specify.

N. OTHER RELEVANT INFORMATION AND COMMENTS

All approvals or denials received from other states, counties or agencies concerning any aspect of equipment operation and efficacy; as well as all safety, competency or training requirements for the users/operators, etc. must also be included.

CERTIFICATION STATEMENT

I certify that the information requested and contained in this document is accurate and complete and that all existing documentation requested in this application for this system or similar systems is provided. The Vendor, identified below, agrees to provide the West Virginia Infectious Medical Waste Program with all results of all studies conducted by or for any state, company, agency or country, or any other person, and all results of all studies which the vendor conducts, or is in any way aware of, to determine the operational performance of any aspect of the equipment for which authorization to operate in this state is requested on the filing of this application. I am aware that infectious medical waste management systems to be operated in this state for infectious medical waste treatment and/or destruction must be identical to the system described in this application for authorization to operate in this state and for which operational data is presented in the application for the West Virginia Infectious Medical Waste Program's review. Any and all changes in the system and related equipment after this application submittal and West Virginia Infectious Medical Waste Program review and authorization to operate must be submitted in writing prior to use.

The West Virginia Infectious Medical Waste Program's permitting conditions or other agency's authorizations granted to operate this system to treat and/or destroy infectious medical waste will be reviewed periodically to ensure specifically authorized infectious medical waste technology systems meet currently accepted standards for infectious medical waste management. The West Virginia Infectious Medical Waste Program may modify system operational or performance requirements for systems that received prior authorizations to operate, if warranted to protect human health and the environment.

I am further aware that on reviewing the completed application and the required attachments, the West Virginia Infectious Medical Waste Program may have additional questions and require submissions of data and other information deemed necessary regarding this or related medical waste disposal systems. Failure to provide all existing requested information will result in delays in processing the request for authorization to operate. Failure to provide all required information as outlined in the application, or willfully withholding information, may be cause for the West Virginia Infectious Medical Waste Program to deny or rescind authorization to operate if it is determined that the information not submitted would have been in any way relevant to its review of this technology.

NAME OF SYSTEM/EQUIPMENT

MODEL NUMBER

NAME OF CERTIFYING PERSON (corporate officer)

TITLE

SIGNATURE OF CERTIFYING PERSON (corporate officer)

DATE

NAME OF PERSON COMPLETING APPLICATION

TITLE

NAME OF VENDER (COMPANY)

TELEPHONE

NAME OF DIVISION

FAX

ADDRESS

EMAIL

CITY, STATE & ZIP CODE

Va.

9VAC20-120-910. Criteria for microbial inactivation.

A. Inactivation is required to be demonstrated of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria at a 6 Log10 reduction or greater; a 6 Log10 reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction).

B. Inactivation is required to be demonstrated of B. stearothermophilus spores or B. subtilis spores at a 4 Log10 reduction or greater; a 4 Log10 reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction).

9VAC20-120-920. Representative of biological indicators.

A. One or more representative microorganisms from each microbial group shall be used in treatment efficacy evaluation.

1. Vegetative Bacteria.

- Staphylococcus aureus (ATCC 6538)

- Pseudomonas aeruginosa (ATCC 15442)

2. Fungi.

- Candida albicans (ATCC 18804)

- Penicillium chrysogenum (ATCC 24791)

- Aspergillus niger

3. Viruses.

- Polio 2 or Polio 3

- MS-2 Bacteriophage (ATCC 15597-B1)

4. Parasites.

- Cryptosporidium spp. oocysts

- Giardia spp. cysts

5. Mycobacteria.

- Mycobacterium terrae

- Mycobacterium phlei

- Mycobacterium bovis (BCG) (ATCC 35743)

B. Spores from one of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems.

1. B. stearothermophilus (ATCC 7953)

2. B. subtilis (ATCC 19659)

9VAC20-120-930. Quantification of microbial inactivation.

A. Microbial inactivation ("kill") efficacy is equated to "Log10 Kill," which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment. This definition is equated as:

Log10 Kill = Log10 I(cfu/g) %68 Log10 R(cfu/g) where:

Log10Kill is equivalent to the term Log10 reduction.

"I" is the number of viable test microorganisms introduced into the treatment unit.

"R" is the number of viable test microorganisms recovered after treatment.

"cfu/g" are colony forming units per gram of waste solids.

B. For those treatment processes that can maintain the integrity of the biological indicator carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, biological indicators of the required strain and concentration can be used to demonstrate treatment efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator.

C. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation/grinding), quantitative measurement of treatment efficacy requires a two step approach: Step 1, "Control"; Step 2, "Test." The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

1. Step 1.

PETITION FOR EVALUATION AND APPROVAL OF
REGULATED MEDICAL WASTE TREATMENT TECHNOLOGY
PART A: GENERAL INFORMATION

Name of Company			
Name of Petitioner (Must be an individual(s) Name)			
Trade Name of Device		Model Number	
Petitioner Address			
City	State	ZIP Code	Petitioner Telephone Number

Department Use Only

Date Application and Questionnaire Received	Date Complete

Note: The review and assessment process will not commence until all information required is submitted by the petitioner and received by the Department.

EVALUATION OF MEDICAL WASTE TREATMENT TECHNOLOGY
INFORMATION REQUEST FORM

Complete the following questionnaire and return it along with the application. Please include any additional support data that may be applicable. Use additional paper if necessary. Reference with the related section and number(s).

A. GENERAL

A1. Is the alternative treatment technology best suited for onsite use at the point of generation, or is it adaptable for use as a commercial or regional treatment process receiving waste from several generators?

? **Onsite** ? **Commercial/Regional** ? **Both**

A2. Is this treatment technology specified for use at small generator facilities such as physician, dental, or veterinary offices or clinics?

? **No** ? **Yes**

A3. Has this alternative treatment technology been approved/disapproved in any other state? If so, please indicate which states have issued a decision and submit copies of approvals/disapprovals.

B. LEVEL OF TREATMENT

B1. Does the level of microbial inactivation achieved by the treeatment process meet the following definition:

"Inactivation of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater, and B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater."?

☐ Yes ☐ No – If no, specify where the definition is unfulfilled.

C. CHARACTERIZATION OF PROPOSED TREATMENT PROCESS

C1. Please check the appropriate categories that best describe the methods of this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

? Chemical	? Heat	? Plasma Arc
? Encapsulation	? Irradiation	? Radiowave
? Grinder	? Mechanical	? Shredder
? Hammermill	? Microwave	

? Other(specify)_____

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

Please identify whether the proposed system is compatible or non-compatible with the following types of waste.

	Types of Waste	Compatible	Non-compatible
D1.	Cultures and stocks of infectious agents and associated biologicals	?	?
D2.	Liquid human and animal waste including blood and blood products and body fluids	?	?
D3.	Human anatomical waste, tissues and body fluids	?	?
D4.	Contaminated waste from animals	?	?
D5.	Sharps	?	?

Please refer to the State medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D6. What waste characteristics present the most challenge to the proposed treatment process?

? Organic materials ? Liquids ? Density/compaction
? Other characteristics (Specify)_____

D7. Describe by composition (i.e., material and percentage) those medical wastes that would provide the most challenge to the proposed technology. Why?

E. BY-PRODUCTS OF THE TREATMENT PROCESS

E1. Please indicate all by-products which may be generated as a result of this alternative treatment technology.

? Air Emissions ? Heat ? Slag ? Vapors or Fumes
? Ash ? Liquid ? Smoke
? Dust ? Odor ? Steam
? Other (Specify) _____

E2. If any of the above by-products are indicated, how will they be controlled?

E3. If there are no by-products indicated, how was this determined?

E4. Are any of these by-products toxic, biohazardous, etc.? ? No ? Yes If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

F. MICROBIALOGICAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, viruses, and mycobacteria at a 6 Log_{10} reduction or greater. A representative from each microbial group is required for testing.

F1. Lister below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. If there are data to support the inactivation of any of the biological indicators using the proposed treatment process under normal operating conditions, please check the appropriate space next to the indicator.

Vegetative Bacteria
- ☐ Staphylococcus aureus (ATCC 6538)
- ☐ Pseudomonas aeruginosa(ATCC 15442)

Fungi
- ☐ Candida albicans(ATCC 18804)
- ☐ Penicillium chrysogenum(ATCC 24791)
- ☐ Aspergillus niger

Viruses
- ☐ Polio 2 or Polio 3
- ☐ MS-2 Bacteriophage (ATCC 15597-Bl)

Parasites
- ☐ Cryptosporidium spp. Oocysts
- ☐ Giardia spp. Cysts

Mycobacteria
- ☐ Mycobacterium terrae
- ☐ Mycobacterium phlei
- ☐ Mycobacterium bovis(BCG)(ATCC 35743)

Bacterial Spores
- ☐ B. stearothermophilus(ATCC 7953)
- ☐ B. subtilis(ATCC 19659)

F. MICROBIOLOGICAL TEST PROCEDURES (CONTINUED)

F1. Were the results certified by an independent, public health or certified testing laboratory?
☐ No ☐ Yes – If so, indicate the name, address, telephone number of the certifying laboratory and attach test protocol and results.

_____
_____
_____
_____
_____

G. CHEMICAL INACTIVATION TREATMENT PROCESSES

G1. If the treatment involves the use of chemical inactivation:
a) What is the name of the active ingredients?_____
b) What concentrations must be used and maintained?_____
c) At what Ph is the chemical agent active?_____
d) What is the necessary contact time?_____
e) If there is any incompatibility with specific materials and surfaces, specify.__

G2. What is the active life of the chemical agent after it has been exposed to air or contaminated medical waste?

_____

G3. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use?
? No ? Yes - If yes, please attach a copy of the study and test results.

G4. What health and safety hazards may be associated with the chemical (present and long-term)? Specify_____
MSDS Attached? ? No ? Yes

G5. Is the chemical agent registered for this specific use with the Environmental Protection Agency (EPA) Pesticide Registration Division?
? No ? Yes - If yes, provide the EPA registration number_____

G6. Is the spent chemical agent classified as a hazardous waste by U.S. EPA (40 CFR Part 261) or by other state criteria?
? No ? Yes - If yes, specify whether by USEPA or which state_____

G7. Is an environmental impact study for the chemical agent available?
? No ? Yes - If yes, attach a copy of this information.

H. ENVIRONMENTAL EFFECTS ON THE TREATMENT PROCESS

H1. Can positive or negative effects on the environment be anticipated from the use and/or disposal of the treated waste from the treatment process?
? No ? Yes - If yes, specify _____

H2. What environmental, occupational, and/or public hazards would be associated with a malfunction of the treatment process? Specify _____

H3. If the treatment process includes the use of water, steam, or other liquids; how will this waste discharge be handled (i.e., sewer, recycle, etc.)?
Specify _____

H4. How will the treated waste from this process be disposed of (i.e., landfill, incineration, recycle, etc.)? Specify _____

H5. Are the by-products identified as a hazardous waste?
? No ? Yes - Complete item M1

I. CRITICAL FACTORS OF TREATMENT PROCESS

I1. What are the critical factors that influence the specific treatment technology?
Specify _____

I2. What are the consequences if these factors are not met?
Specify _____

I3. Explain the ease and/or difficulty of operation of the medical waste treatment system?
Specify_____

I4. What type of ongoing maintenance is required in the operation of the treatment system?
Specify_____
Maintenance Manual Attached? ? No ? Yes

I5. What emergency measures would be required in the event of a malfunction?
Specify _____

I6. Are these measures addressed in an emergency plan or in the operations protocol?
? No ? Yes - If yes, attach a copy

I7. What is the maximum amount of waste to be treated by this process per cycle?
_____

I8. How long is a cycle? _____

J. QUALITY ASSURANCE AND VERIFICATION OF ADEQUATE TREATMENT

J1. How is the quality assurance of the treatment process addressed?
Specify _____

J2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system?
Specify _____

J3. Other than the biological indicators listed in Section F, what other indicators, integrators, or monitoring devices would be used to show that the treatment unit or process was functioning properly? (Please describe and explain.)

J4. How is it determined that the processed waste has received proper treatment? (Check the appropriate item.)

Temperature indicator:	?	Visual only	?	Continuous	?	Both
Pressure indicator:	?	Visual only	?	Continuous	?	Both
Time indicator:	?	Visual only	?	Continuous	?	Both
Chemical concentration indicator:	?	Visual only	?	Continuous	?	Both

? Other - Please specify _____

J5. Have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process?
Specify _____

J6. Is there a process monitor calibration schedule established, and at what frequency is calibration performed?

J7. Are the process monitors interfaced to the system's operations to effect proper treatment conditions? Explain.

J8. Are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately effected? Explain.

K. POST TREATMENT RECYCLING

K1. Has a strategy been developed for the recycling of any part of the treated waste?
☐ No ☐ Yes If yes, please include additional information regarding the strategy.

L. COMPLIANCE WITH MEDICAL WASTE REGULATIONS

L1. Does your treatment technology meet the requirements of the State's medical waste regulations for medical waste decontamination and disposal?
? No ? Yes

L2. Which of the following five categories of medical waste will be effectively treated by your system? (Check all that apply.)

		NO	YES
a)	Cultures and Stocks	?	?
b)	Blood and Blood Products and Body Fluids	?	?
c)	Human Anatomical Waste, Human Tissues and Body Fluids	?	?
d)	Sharps	?	?
e)	Contaminated Animal Wastes	?	?

M. INTERAGENCY COORDINATION

M1. Have you inquired from the State's medical waste permit coordinator as to whether any other permits are required? ? No ? Yes
If yes, please enclose the response and requirements with your application.

NOTE: Local governments may require permits.

N. POTENTIAL ENVIRONMENTAL BENEFITS

N1. Has an energy analysis been conducted on the proposed technology?

? No ? Yes - If yes, specify and provide results of that analysis.

N2. Has an economic analysis been performed on the proposed technology?

? No ? Yes - If yes, specify and provide results of that analysis.

N3. How does this treatment technology improve on existing medical waste treatment and disposal methods?

Specify _____

N4. What is the potential of this proposed technology for:

Waste volume reduction? Specify _____

Recycling? Specify _____

O. OTHER RELEVANT INFORMATION AND COMMENTS

(Approvals received from other states, operator safety, competency or training requirements for the users/operators, etc.)

PETITION FOR EVALUATION AND APPROVAL OF REGULATED MEDICAL WASTE TREATMENT TECHNOLOGY
PART B: ATTACHMENTS

The general information contained in Part A and this check sheet are a required part of the petition package. These assist the petitioner in submitting the petition and the Department in its review, and they are supplemental to the required documents listed below. The complete petition package consists of a completed Part A form, this Part B check sheet, all the documents listed below, and any other supportive data or information the petitioner wishes to be considered.

? Petitioner's submittal certification

? Quality Assurance and Quality Control Report

? Microbiological testing report

? Material Safety Data Sheets

? Environmental Protection Agency pesticide registration documents

? Maintenance manual

? Emergency operations manual

? Operations manual

? Design plans and specification

DAR File No. 29215

This filing was published in the 12/01/2006, issue, Vol. 2006, No. 23, of the Utah State Bulletin.

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Environmental Quality, Solid and Hazardous Waste

R315-316

Infectious Waste Requirements

NOTICE OF PROPOSED RULE

DAR File No.: 29215
Filed: 11/09/2006, 03:28
Received by: NL

RULE ANALYSIS

Purpose of the rule or reason for the change:
The rule is changed to make it easer to find requirements for approval of an alternative treatment method and to clarify storage.

Summary of the rule or change:
Rule language outlining the requirements for an alternative treatment approval is moved from the applicability section to the treatment and disposal section. Storage wording is clarified.

State statutory or constitutional authorization for this rule:
Section 19-6-105

Anticipated cost or savings to:
the state budget:
The rule change does not affect state agencies and the enforcement and oversight of the rule will not change. Therefore, no cost or saving impact is anticipated for the state budget.

local governments:
Since the requirements of the rule are clarified and not changed, there is no cost or savings impact anticipated for local governments.

other persons:
Since the requirements of the rule are clarified and not changed, there is no cost or savings impact anticipated for other persons.

Compliance costs for affected persons:

Since the requirements of the rule are clarified and not changed, no compliance cost or savings impact for affected persons is expected beyond that required by current statute or rule as a result of the proposed rule change.

Comments by the department head on the fiscal impact the rule may have on businesses:
Since the requirements of the rule are clarified and not changed, no compliance cost or savings impact for businesses is expected beyond that required by current statute or rule as a result of the proposed rule change. Dianne R. Nielson, Executive Director

The full text of this rule may be inspected, during regular business hours, at the Division of Administrative Rules, or at:
Environmental Quality
Solid and Hazardous Waste
288 N 1460 W
SALT LAKE CITY UT 84116-3231

Direct questions regarding this rule to:
Ralph Bohn at the above address, by phone at 801-538-6794, by FAX at 801-538-6715, or by Internet E-mail at Rbohn@utah.gov

Interested persons may present their views on this rule by submitting written comments to the address above no later than 5:00 p.m. on:
01/02/2007

This rule may become effective on:
01/31/2007

Authorized by:
Dennis Downs, Director

RULE TEXT

R315. Environmental Quality, Solid and Hazardous Waste.

R315-316. Infectious Waste Requirements.

R315-316-1. Applicability.

(1) The standards of Rule R315-316 apply to:

(a) any health facility as defined by Subsection 19-6-102(10) that generates more than 200 pounds, per month, of infectious waste as defined by Subsection 19-6-102(12);

(b) any transporter that collects and transports more than 200 pounds of infectious waste in any one load; and

(c) a storage, treatment, or disposal facility.

(2) The standards of Rule R315-316 do not apply to a health facility that generates 200 pounds, or less, of infectious waste per month.[

~~(3) All material that has been rendered non-infectious may be handled as non-infectious waste, provided it is not an otherwise regulated hazardous or radioactive waste and is not subject to the requirements of Rule R315-316.~~

~~(a) Except for incineration and steam sterilization, no treatment method may be used to render materials non-infectious without receiving approval from the Executive Secretary.~~

~~(b) Prior to its use, the Executive Secretary shall make a determination, on a site specific basis, that the proposed treatment method renders materials non-infectious.~~

~~(c) The determination shall be based on the results of laboratory tests, submitted by the person proposing the use of the treatment method, meeting the following requirements:~~

~~(i) the laboratory tests shall be conducted:~~

~~(A) by qualified laboratory personnel;~~

~~(B) using recognized microbial techniques;~~

~~(C) on samples that have been inoculated with the test organisms, then subjected to the proposed treatment method and processed the same way as will be used in the treatment process if approved; and~~

~~(ii) the results of the tests must document that the proposed treatment method inactivates:~~

~~(A) vegetative bacteria - Staphylococcus aureus (ATCC 6538) or Pseudomonas aeruginosa (ATCC 15442) at a 6 Log_{10} reduction or greater (a 99.9999% reduction or greater of the organism population);~~

~~(B) fungi - Candida albicans (ATCC 18804), Penicillium chrysogenum (ATCC 24791), or Aspergillus niger at a 6 Log_{10} reduction or greater;~~

~~(C) viruses - Polio 2, Polio 3, or MS-2 Bacteriophage (ATCC15597-B1) at a 6 Log_{10} reduction or greater;~~

~~(D) parasites - Cryptosporidium spp. oocysts or Giardia spp. cysts at a 6 Log_{10} reduction or greater;~~

~~(E) mycobacteria - Mycobacterium terrae, Mycobacterium phlei, or Mycobacterium bovis (BCG) (ATCC 35743) at a 6 Log_{10} reduction or greater; and~~

~~(B) Bacterial spores - Bacillus stearothermophilus spores (ATCC 7953) or Bacillus subtilis spores (ATCC 19659) at a 4 Log_{10} reduction or greater (a 99.99% reduction or greater of the organism population).~~

~~(iii) The Executive Secretary shall review the submitted materials and reply in writing within 30 days of the receipt of the submittal.~~]

R315-316-3. Storage and Containment Requirements.

(1) Containment shall be in a manner and location which affords protection from animal intrusion, does not provide a breeding place or a food source for insects [~~and~~]or rodents, and minimizes exposure to the public.

(2) Unless all waste is considered infectious and labeled as such, infectious waste shall be segregated by separate containment from other waste [~~at the point of origin~~]during storage.

(3) Except for sharps, infectious waste shall be contained in plastic bags or inside rigid containers. The bags shall be securely tied and the containers shall be securely sealed to prevent leakage or expulsion of solid or liquid wastes during storage, handling, or transport.

(4) Sharps shall be contained for storage, transportation, treatment, and disposal in leak-proof, rigid, puncture-resistant containers which are taped closed or tightly lidded to preclude loss of contents.

(5) All containers used for containment of any infectious waste shall be red or orange, or if containers are not red or orange, shall be clearly identified with the international biohazard sign and one of the following labels: "INFECTIOUS WASTE", "BIOMEDICAL WASTE", or "BIOHAZARD".

(6) If other waste is placed in the same container as [~~regulated~~] infectious waste, then the generator must package, label, and mark the container and its entire contents as infectious waste.

(7) A rigid infectious waste container may be reused for infectious or non-infectious waste if it is thoroughly washed and decontaminated each time it is emptied or if the surfaces of the container have been completely protected from contamination by disposable, unpunctured, or undamaged liners, bags, or other devices that are removed with the infectious waste, and the surface of the liner has not been damaged or punctured.

(8) Storage and containment areas [~~must~~]shall: protect infectious waste from the elements[~~,~~]; be ventilated to the outside[~~,~~]; be only accessible to authorized persons[~~,~~]; and be marked with prominent warning signs on, or adjacent to, the exterior doors or gates. The warning signs shall contain the international biohazard sign and shall state: "CAUTION -- INFECTIOUS WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and must be easily read during daylight from a distance of 25 feet.

(9) If infectious waste is stored longer than seven days, it shall be stored at 40 degrees Fahrenheit (5 degrees Celsius), or below[~~, but must be treated or disposed within 30 days~~].

(10) Under no conditions may infectious waste be stored for longer than 30 days.

[~~(10)~~](11) Compactors, grinders, or similar devices shall not be used to reduce the volume of infectious waste before the waste has been rendered non-infectious unless the device is contained sufficiently to prevent contamination of the surrounding area.

R315-316-5. Infectious Waste Treatment and Disposal Requirements.

(1) Infectious waste shall be treated or disposed as soon as possible but not to exceed 30 days after generation, and shall be treated or disposed at a facility with a permit or other form of approval allowing the facility to treat or dispose infectious waste.

(2)(a) All material that has been rendered non-infectious through an approved treatment method may be handled as non-infectious waste, provided it is not otherwise a hazardous waste or radioactive waste excluded from disposal in a solid waste facility by Rule R315-316.

(b) Except for incineration and steam sterilization, no treatment method may be used to render materials non-infectious without receiving prior approval from the Executive Secretary.

[~~(2)~~](3) Infectious waste may be incinerated in an incinerator.

(a) The incinerator shall comply with the requirements of Rule R315-306 and provide complete combustion of the waste to carbonized or mineralized ash.

(b) A composite sample of the ash and residues from the incinerator shall be taken at least once each year. The sample shall be analyzed by the U.S. EPA Test Method 1311 as provided in 40 CFR Part 261, Appendix II, 1991 ed., Toxic Characteristics Leaching Procedure (TCLP) on parameters determined by the Executive Secretary to determine if it is a hazardous waste. If hazardous, it shall be managed by applicable state regulations.

[~~(3)~~](4) Infectious waste may be sterilized by heating in a steam sterilizer to render the waste non-infectious.

(a) The operator shall have available and shall certify in writing that he understands written operating procedures for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity.

(b) Infectious waste shall be subjected to sufficient temperature, pressure and time to inactivate Bacillus stearothermophilus spores in the center of the waste load at a 6 Log_{10} reduction or greater.

(c) Unless a steam sterilizer is equipped to continuously monitor and record temperature and pressure during the entire length of each sterilization cycle, each package of infectious waste to be sterilized shall have a temperature sensitive tape or equivalent test material, such as chemical indicators, attached that will indicate if the sterilization temperature and pressure have been reached. Waste shall not be considered sterilized if the tape or equivalent indicator fails to indicate that a temperature of at least 250 degrees Fahrenheit (121 degrees Celsius) was reached during the process.

(d) Each sterilization unit shall be evaluated for effectiveness with spores of B. stearothermophilus at least once each 40 hours of operation or each week, whichever is less.

(e) A written log for each load shall be maintained for each sterilization unit which shall contain at a minimum:

(i) the time of day, date, and operator's name;

(ii) the amount and type of infectious waste placed in the sterilizer; and

(iii) the temperature and duration of treatment.

(5)(a) Alternative treatment methods may be approved on a site-specific basis when the Executive Secretary finds the proposed alternative treatment method renders the material non-infectious.

(b) The determination shall be based on the results of laboratory tests, submitted by the person proposing the use of the treatment method, meeting the following requirements:

(i) the laboratory tests shall be conducted:

(A) by qualified laboratory personnel;

(B) using recognized microbial techniques;

(C) on samples that have been inoculated with the test organisms, then subjected to the proposed treatment method and processed the same way as will be used in the treatment process if approved; and

(ii) the results of the tests must document that the proposed treatment method inactivates:

(A) vegetative bacteria - Staphylococcus aureus (ATCC 6538) or Pseudomonas aeruginosa (ATCC 15442) at a 6 Log_{10} reduction or greater (a 99.9999% reduction or greater of the organism population);

(B) fungi - Candida albicans (ATCC 18804), Penicillium chrysogenum (ATCC 24791), or Aspergillus niger at a 6 Log_{10} reduction or greater;

(C) viruses - Polio 2, Polio 3, or MS-2 Bacteriophage (ATCC15597-B1) at a 6 Log_{10} reduction or greater;

(D) parasites - Cryptosporidium spp. oocysts or Giardia spp. cysts at a 6 Log_{10} reduction or greater;

(E) mycobacteria - Mycobacterium terrae, Mycobacterium phlei, or Mycobacterium bovis (BCG) (ATCC 35743) at a 6 Log_{10} reduction or greater; and

(B) Bacterial spores - Bacillus stearothermophilus spores (ATCC 7953) or Bacillus subtilis spores (ATCC 19659) at a 4 Log_{10} reduction or greater (a 99.99% reduction or greater of the organism population).

(iii) The Executive Secretary shall review the submitted materials and reply in writing within 30 days of the receipt of the submittal.

[~~(4)~~](6) Infectious waste may be discharged to a sewage treatment system that provides secondary treatment of waste but only if the waste is liquid or semi-solid and if approved by the operator of the sewage treatment system.

[~~(5)~~](7) Infectious waste may be disposed in a permitted Class I, II, or V Landfill. Upon entering the landfill, the transporter of infectious waste shall notify the landfill operator that the load contains infectious waste. The landfill operator shall abide by the following procedures in the disposition and covering of infectious waste:

(a) place the infectious waste containers at the bottom of the working face with sufficient care to avoid breaking them;

(b) completely cover the infectious waste immediately with a minimum of 12 inches of earth or waste material containing no infectious waste; and

(c) not compact the infectious waste until completely covered with 12 inches of earth or waste material containing no infectious waste.

KEY: solid waste management, waste disposal

Date of Enactment or Last Substantive Amendment: [~~October 15, 2003~~]2007

Notice of Continuation: March 14, 2003

Authorizing, and Implemented or Interpreted Law: 19-6-105

ADDITIONAL INFORMATION

Text to be deleted is struck through and surrounded by brackets (e.g., [~~example~~]). Text to be added is *underlined* (e.g., example). Older browsers may not depict some or any of these attributes on the screen or when the document is printed.

For questions regarding the *content* or *application* of this rule, please contact Ralph Bohn at the above address, by phone at 801-538-6794, by FAX at 801-538-6715, or by Internet E-mail at Rbohn@utah.gov

For questions about the *rulemaking process*, please contact the Division of Administrative Rules (801-538-3764).
Please Note: The Division of Administrative Rules is *NOT* able to answer questions about the content or application of these administrative rules.

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Last modified: 11/29/2006 11:05 AM

R315. Environmental Quality, Solid and Hazardous Waste.
R315-316. Infectious Waste Requirements.
R315-316-1. Applicability.

(1) The standards of Rule R315-316 apply to:

(a) any health facility as defined by Subsection 19-6-102(10) that generates more than 200 pounds, per month, of infectious waste as defined by Subsection 19-6-102(12);

(b) any transporter that collects and transports more than 200 pounds of infectious waste in any one load; and

(c) a storage, treatment, or disposal facility.

(2) The standards of Rule R315-316 do not apply to a health facility that generates 200 pounds, or less, of infectious waste per month.

R315-316-2. General Operational Requirements.

(1) Every facility that generates, transports, stores, treats, or disposes of infectious waste must prepare and maintain on file a management plan for the waste that identifies the:

(a) type and estimated quantity of waste generated or handled;

(b) segregation, packaging, and labeling procedures;

(c) collection, storage, and transportation procedures, including the name of the transporter, to be implemented;

(d) treatment or disposal methods that will be used, and disposal facility that will be used; and

(e) person responsible for the management of the infectious waste.

(2) All infectious waste generators and handlers shall report any delivery of unauthorized waste to the local health department immediately upon recognition.

(3) Infectious waste consisting of recognizable human anatomical remains including human fetal remains shall be disposed by incineration or interment.

R315-316-3. Storage and Containment Requirements.

(1) Containment shall be in a manner and location which affords protection from animal intrusion, does not provide a breeding place or a food source for insects or rodents, and minimizes exposure to the public.

(2) Unless all waste is considered infectious and labeled as such, infectious waste shall be segregated by separate containment from other waste during storage.

(3) Except for sharps, infectious waste shall be contained in plastic bags or inside rigid containers. The bags shall be securely tied and the containers shall be securely sealed to prevent leakage or expulsion of solid or liquid wastes during storage, handling, or transport.

(4) Sharps shall be contained for storage, transportation, treatment, and disposal in leak-proof, rigid, puncture-resistant containers which are taped closed or tightly lidded to preclude loss of contents.

(5) All containers used for containment of any infectious waste shall be red or orange, or if containers are not red or orange, shall be clearly identified with the international

biohazard sign and one of the following labels: "INFECTIOUS WASTE", "BIOMEDICAL WASTE", or "BIOHAZARD".

(6) If other waste is placed in the same container as infectious waste, then the generator must package, label, and mark the container and its entire contents as infectious waste.

(7) A rigid infectious waste container may be reused for infectious or non-infectious waste if it is thoroughly washed and decontaminated each time it is emptied or if the surfaces of the container have been completely protected from contamination by disposable, unpunctured, or undamaged liners, bags, or other devices that are removed with the infectious waste, and the surface of the liner has not been damaged or punctured.

(8) Storage and containment areas shall: protect infectious waste from the elements; be ventilated to the outside; be only accessible to authorized persons; and be marked with prominent warning signs on, or adjacent to, the exterior doors or gates. The warning signs shall contain the international biohazard sign and shall state: "CAUTION -- INFECTIOUS WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and must be easily read during daylight from a distance of 25 feet.

(9) If infectious waste is stored longer than seven days, it shall be stored at 40 degrees Fahrenheit (5 degrees Celsius), or below.

(10) Under no conditions may infectious waste be stored for longer than 30 days.

(11) Compactors, grinders, or similar devices shall not be used to reduce the volume of infectious waste before the waste has been rendered non-infectious unless the device is contained sufficiently to prevent contamination of the surrounding area.

R315-316-4. Infectious Waste Transportation Requirements.

(1) Infectious waste shall not be transported in the same vehicle with other waste unless the infectious waste is contained in a separate, fully enclosed leak-proof container within the vehicle compartment or unless all of the waste is to be treated as infectious waste in accordance with this section.

(2) Persons manually loading or unloading containers of infectious waste onto or from transport vehicles shall:

(a) be trained in the proper use of protective equipment;

(b) have available and easily accessible at all times puncture resistant gloves and shoes, shatterproof glasses, and coveralls; and

(c) have face shields and respirators available as deemed necessary by the transporter.

(d) Protective gear that becomes soiled shall be decontaminated or disposed as infectious waste.

(3) Surfaces of transport vehicles that have contacted spilled or leaked infectious waste shall be decontaminated by procedures approved by the Executive Secretary.

(4) Transport vehicles transporting infectious waste shall meet all warning requirements of the Department of Transportation.

(5) Each truck, trailer, or semitrailer, or container used for transporting infectious waste shall be so designed and constructed, and its contents limited so that under conditions

normally incident to transportation, there shall be no releases of infectious waste to the environment.

(6) Any truck, trailer, semitrailer, or container used for transporting infectious waste shall be free from leaks, and all discharge openings shall be securely closed during transportation.

(7) No person shall transport infectious waste into the state for treatment, storage, or disposal unless the waste is packaged, contained, labeled and transported in the manner required by this section.

(8) All transporter vehicles shall carry a spill containment and cleanup kit and the transport workers shall be trained in spill containment and cleanup procedures.

R315-316-5. Infectious Waste Treatment and Disposal Requirements.

(1) Infectious waste shall be treated or disposed as soon as possible but not to exceed 30 days after generation, and shall be treated or disposed at a facility with a permit or other form of approval allowing the facility to treat or dispose infectious waste.

(2)(a) All material that has been rendered non-infectious through an approved treatment method may be handled as non-infectious waste, provided it is not otherwise a hazardous waste or radioactive waste excluded from disposal in a solid waste facility by Rule R315-316.

(b) Except for incineration and steam sterilization, no treatment method may be used to render materials non-infectious without receiving prior approval from the Executive Secretary.

(3) Infectious waste may be incinerated in an incinerator.

(a) The incinerator shall comply with the requirements of Rule R315-306 and provide complete combustion of the waste to carbonized or mineralized ash.

(b) A composite sample of the ash and residues from the incinerator shall be taken at least once each year. The sample shall be analyzed by the U.S. EPA Test Method 1311 as provided in 40 CFR Part 261, Appendix II, 1991 ed., Toxic Characteristics Leaching Procedure (TCLP) on parameters determined by the Executive Secretary to determine if it is a hazardous waste. If hazardous, it shall be managed by applicable state regulations.

(4) Infectious waste may be sterilized by heating in a steam sterilizer to render the waste non-infectious.

(a) The operator shall have available and shall certify in writing that he understands written operating procedures for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure on container, pattern of loading, water content, and maximum load quantity.

(b) Infectious waste shall be subjected to sufficient temperature, pressure and time to inactivate Bacillus stearothermophilus spores in the center of the waste load at a 6 Log_{10} reduction or greater.

(c) Unless a steam sterilizer is equipped to continuously monitor and record temperature and pressure during the entire length of each sterilization cycle, each package of infectious waste to be sterilized shall have a temperature sensitive tape or equivalent test material, such as chemical indicators, attached

that will indicate if the sterilization temperature and pressure have been reached. Waste shall not be considered sterilized if the tape or equivalent indicator fails to indicate that a temperature of at least 250 degrees Fahrenheit (121 degrees Celsius) was reached during the process.

(d) Each sterilization unit shall be evaluated for effectiveness with spores of B. stearothermophilus at least once each 40 hours of operation or each week, whichever is less.

(e) A written log for each load shall be maintained for each sterilization unit which shall contain at a minimum:

(i) the time of day, date, and operator's name;

(ii) the amount and type of infectious waste placed in the sterilizer; and

(iii) the temperature and duration of treatment.

(5)(a) Alternative treatment methods may be approved on a site-specific basis when the Executive Secretary finds the proposed alternative treatment method renders the material non-infectious.

(b) The determination shall be based on the results of laboratory tests, submitted by the person proposing the use of the treatment method, meeting the following requirements:

(i) the laboratory tests shall be conducted:

(A) by qualified laboratory personnel;

(B) using recognized microbial techniques;

(C) on samples that have been inoculated with the test organisms, then subjected to the proposed treatment method and processed the same way as will be used in the treatment process if approved; and

(ii) the results of the tests must document that the proposed treatment method inactivates:

(A) vegetative bacteria - Staphylococcus aureus (ATCC 6538) or Pseudomonas aeruginosa (ATCC 15442) at a 6 Log_{10} reduction or greater (a 99.9999% reduction or greater of the organism population);

(B) fungi - Candida albicans (ATCC 18804), Penicillium chrysogenum (ATCC 24791), or Aspergillus niger at a 6 Log_{10} reduction or greater;

(C) viruses - Polio 2, Polio 3, or MS-2 Bacteriophage (ATCC15597-B1) at a 6 Log_{10} reduction or greater;

(D) parasites - Cryptosporidium spp. oocysts or Giardia spp. cysts at a 6 Log_{10} reduction or greater;

(E) mycobacteria - Mycobacterium terrae, Mycobacterium phlei, or Mycobacterium bovis (BCG) (ATCC 35743) at a 6 Log_{10} reduction or greater; and

(B) Bacterial spores - Bacillus stearothermophilus spores (ATCC 7953) or Bacillus subtilis spores (ATCC 19659) at a 4 Log_{10} reduction or greater (a 99.99% reduction or greater of the organism population).

(iii) The Executive Secretary shall review the submitted materials and reply in writing within 30 days of the receipt of the submittal.

(6) Infectious waste may be discharged to a sewage treatment system that provides secondary treatment of waste but only if the waste is liquid or semi-solid and if approved by the operator of

the sewage treatment system.

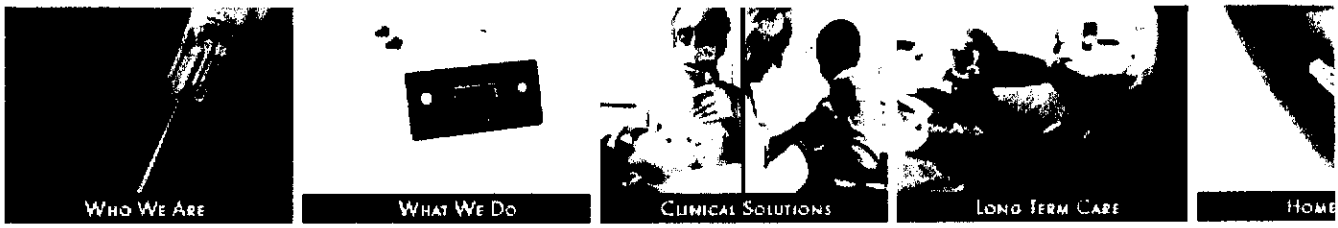
(7) Infectious waste may be disposed in a permitted Class I, II, or V Landfill. Upon entering the landfill, the transporter of infectious waste shall notify the landfill operator that the load contains infectious waste. The landfill operator shall abide by the following procedures in the disposition and covering of infectious waste:

(a) place the infectious waste containers at the bottom of the working face with sufficient care to avoid breaking them;

(b) completely cover the infectious waste immediately with a minimum of 12 inches of earth or waste material containing no infectious waste; and

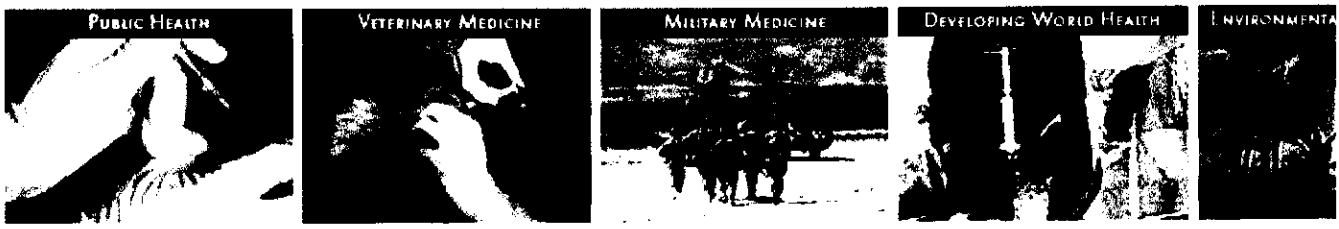
(c) not compact the infectious waste until completely covered with 12 inches of earth or waste material containing no infectious waste.

KEY: solid waste management, waste disposal
Date of Enactment or Last Substantive Amendment: February 1, 2007
Notice of Continuation: March 14, 2003
Authorizing, and Implemented or Interpreted Law: 19-6-105



BioMedical Technology Solutions, Inc.

Innovative solutions to biomedical waste management



BioMedical Technology Solutions, Inc.
9800 Mt. Pyramid Court, Suite 350
Englewood, CO 80112
Toll Free: 866.525.BMTS | Phone: 303-653-0100 | Fax: 303-653-0120

Who We Are | What We Do | Clinical Solutions | Long Term Care | Home Health
Public Health | Veterinary Medicine | Military Medicine | Developing World Health | Environmental Responsibility | Cont

EXHIBIT B

BMTS™

BioMedical Technology So
Innovative solutions to biomedical waste ma

- Home
- Who We Are
- What We Do
- Clinical Solutions
- Long-Term Care
- Home Health
- Public Health
- Veterinary Medicine
- Military Medicine
- Developing World Healthcare
- Environmental Responsibility

Regulatory Compliance

The Demolizer® II system is designed to meet or exceed the standards or guidelines for biomedical waste treatment by the EPA, CDC and OSHA.

Laws and regulations for medical waste treatment and disposal are managed at the state or local level. The Demolizer® technology has been reviewed by over 76 governmental agencies and is either formallly approved or meets regualatory requriements for treatment in 46 U.S. states.

U.S. State Regulatory Compliance

Safety
Simplicity
Savings
Operation
Applications
Specification
Performance
Technical Su
Perpetual Lia
Regulatory Compliance
State Approv
Collector Tec
Patents
View Demoli Brochure

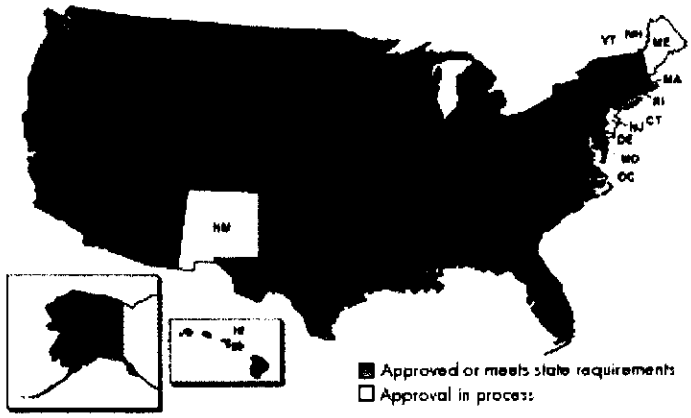
BMTS

BioMedical Technology So
Innovative solutions to biomedical waste ma

- Home
- Who We Are
- What We Do
- Clinical Solutions
- Long-Term Care
- Home Health
- Public Health
- Veterinary Medicine
- Military Medicine
- Developing World Healthcare
- Environmental Responsibility

State Approvals

The Demolizer® system is approved or meets the regulatory requirements for treatment as an alternative medical waste treatment device in the following states



The Demolizer® system is either formally approved or meets the requirements for medical waste treatment and disposal in 46 U.S. states.

The information above is not intended to be an endorsement of the Demolizer® technology by any state or local agency.

For more information on the use of the Demolizer® II System in your location, please complete the form below or contact BMTS at 1-866-525-BMTS.

* = Required Item

* Name

* Facility Name

Type of Facility

Address

* City State Zip Code

Safety
Simplicity
Savings
Operation
Applications
Specification:
Performance
Technical Su
Perpetual Lia
Regulatory Compliance
State Approv
Collector Tec
Patents
View Demoliz Brochure

Telephone

* Email Address

Fax

Preferred Means of Delivery (email, fax, post):

* Are You a Current Demolizer™ user?
(Yes/No)

Comments

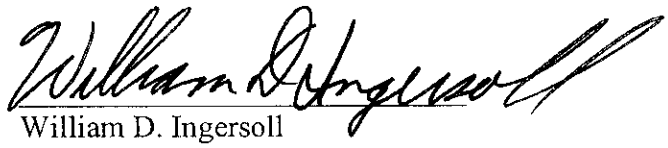
SUBMIT RESET

CERTIFICATE OF SERVICE

I, the undersigned attorney at law, hereby certify that on December 26, 2007 I served A true and correct copy of the **AMENDED RECOMMENDATION OF THE ILLINOIS EPA**, by placing true and correct copies in properly sealed and addressed envelope and by depositing said sealed envelope in a U.S. mail drop box located within Springfield, Illinois, with sufficient Certified Mail postage affixed thereto, upon the following named persons:

Dorothy M. Gunn, Clerk
Illinois Pollution Control Board
James R. Thompson Center
100 West Randolph Street
Suite 11-500
Chicago, IL 60601

GREENBERG TRAURIG, LLP
Attn: Neal H. Weinfield , Esq.
77 West Wacker Drive, Suite 2500
Chicago, Illinois 60601



William D. Ingersoll