

**RECEIVED**  
CLERK'S OFFICE

DEC 28 2007

STATE OF ILLINOIS  
Pollution Control Board

**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**

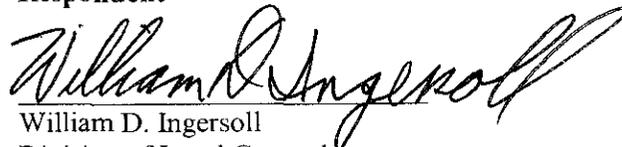
Dorothy M. Gunn, Clerk  
Illinois Pollution Control Board  
James R. Thompson Center  
100 West Randolph Street  
Suite 11-500  
Chicago, IL 60601

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

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

Respectfully submitted,

**ILLINOIS ENVIRONMENTAL PROTECTION  
AGENCY,  
Respondent**



William D. Ingersoll  
Division of Legal Counsel  
1021 North Grand Avenue, East  
P.O. Box 19276  
Springfield, Illinois 62794-9276  
217/782-5544  
217/782-9143 (TDD)

Dated: December 24, 2007

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 )

DEC 28 2007  
STATE OF ILLINOIS  
Pollution Control Board

**ILLINOIS EPA RECOMMENDATION**

The ILLINOIS ENVIRONMENTAL PROTECTION AGENCY ("Illinois EPA"), by its attorney William Ingersoll, hereby submits its Recommendation in the above captioned matter. 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<sup>®</sup>, 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 be 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 ATCC 19659 as an appropriate bacterial spore. (Exh. XX) 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<sup>®</sup> 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<sup>®</sup> or for which the Demolizer<sup>®</sup> meets statutory requirements ..." ) is suspect, in general, since such a contention is that of the 46 states, the Demolizer<sup>®</sup> "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](http://www.bmtscorp.com)) the Demolizer<sup>®</sup> 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](http://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. XX )
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<sup>®</sup> 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<sup>1</sup>. 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<sup>®</sup> or for which the Demoizer<sup>®</sup> meets statutory requirements, Illinois is the only state that has required use of the Chemical Indicator in the IET for the Demolizer<sup>®</sup> 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

---

<sup>1</sup> 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.

had 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:

Section 1422. TABLE B Indicator Microorganisms

1. *Bacillus subtilis* (ATCC 19659) ...

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

##### **STATEMENT OF IMPLEMENTATION OF FEDERAL REQUIREMENTS**

###### **35 Ill. Adm. Code 104.406(b)**

18. This regulation of general applicability was not promulgated to implement, in whole or 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 JUSTIFICATION**  
**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 ENVIRONMENT**

**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  
Division of Legal Counsel

DATED: December 24, 2007  
1021 North Grand Ave. East  
P.O. Box 19276  
Springfield, Illinois 62794-9276  
217/782-5544

## CERTIFICATE OF SERVICE

I, the undersigned attorney at law, hereby certify that on December 24, 2007 I served true and correct copies of an **APPERANCE and 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 TRAUIG, LLP  
Attn: Neal H. Weinfield, Esq.  
77 West Wacker Drive, Suite 2500  
Chicago, Illinois 60601

  
William D. Ingersoll