

ILLINOIS POLLUTION CONTROL BOARD

April 3, 2008

IN THE MATTER OF:)
)
PETITION OF BIOMEDICAL) AS 08-6
TECHNOLOGY SOLUTIONS INC. FOR AN) (Adjusted Standard – PIMW)
ADJUSTED STANDARD FROM 35 ILL.)
ADM. CODE 1422)

OPINION AND ORDER OF THE BOARD (by N.J. Melas):

Biomedical Technology Solutions, Inc. (BMTS) filed a petition (Pet.) for a statewide adjusted standard from the testing requirements for units treating potentially infectious medical waste (PIMW) at 35 Ill. Adm. Code 1422. Appendix A, Table B. BMTS, based in Colorado, is pursuing the Illinois market to sell its Demolizer® unit, a countertop medical waste treatment device for treating PIMW. The Demolizer® unit uses dry heat to sterilize PIMW, including needles, and render it into a non-recognizable solid waste.

The Illinois PIMW regulations at 35 Ill. Adm. Code 1422. Appendix A include test procedures for verifying effective sterilization using an Initial Efficacy Test (IET). Section 1422. Table B lists three indicator microorganisms to be used in the IET. As clarified in an amended petition, (Am. Pet.) BMTS requests permission to use a different indicator organism than any listed in the PIMW rules to prove effective sterilization: *Bacillus atrophaeus* ATCC¹ 9372.

Consistent with the December 28, 2007 Recommendation (Rec.) and December 31, 2007 Amended Recommendation (Am. Rec.) of the Illinois Environmental Protection Agency (Agency), the Board finds that BMTS has justified its request for adjusted standard. The Board today grants the adjusted standard in language similar to that suggested by the Agency.

LEGAL FRAMEWORK

Section 28.1 of the Environmental Protection Act (Act) and Board rules provide that a petitioner may request, and the Board may grant, an environmental standard that is different from the generally applicable regulation that otherwise applies to that petitioner. See 415 ILCS 5/28.1(a) (2006); 35 Ill. Adm. Code 104.400(a), 104.402. This form of regulatory relief is called an adjusted standard.

The procedures that govern an adjusted standard proceeding are found in Section 28.1 of the Act and Part 104, Subpart D of the Board’s procedural rules. See 415 ILCS 5/28.1 (2006);

¹ ATCC refers to the American Type Culture Collection, an international nonprofit organization that provides biological products and technical services to the scientific community. The biological samples deposited with the ATCC are used internationally as the reference standard for biological materials. See Pet. at 3, n. 1, and 35 Ill. Adm. Code 1420.102 defining “ATCC”.

35 Ill. Adm. Code 104.400-104.428. The adjusted standard proceeding is adjudicatory in nature and therefore not subject to the rulemaking provisions of the Act or the Illinois Administrative Procedure Act (5 ILCS 100 (2006)). *See* 415 ILCS 5/28.1(a) (2006); 35 Ill. Adm. Code 101.202. Once a petition for an adjusted standard is filed, the Agency must file its recommendation with the Board. *See* 415 ILCS 5/28.1(d)(3) (2006); 35 Ill. Adm. Code 104.416. The Board's procedural rules specify the required contents for the adjusted standard petition and the Agency recommendation. *See* 35 Ill. Adm. Code 104.406, 104.416.

Section 28.1(d)(1) of the Act (415 ILCS 5/28.1 (2006)) and Section 104.408(a) of the Board's procedural rules (35 Ill. Adm. Code 104.408(a) (quoting the Act)) require the adjusted standard petitioner to publish notice of the petition's filing by advertisement in a newspaper of general circulation in the area likely to be affected by the proposed adjusted standard. Under those provisions, publication must take place within 14 days after the petition is filed. The newspaper notice must indicate that any person may cause a public hearing to be held on the proposed adjusted standard by filing a hearing request with the Board within 21 days after publication. *See* 415 ILCS 5/28.1(d)(1) (2006); 35 Ill. Adm. Code 104.408(b).

The burden of proof in an adjusted standard proceeding is on petitioner. *See* 415 ILCS 5/28.1(b), (c) (2006); 35 Ill. Adm. Code 104.426. Once granted, the adjusted standard applies to petitioner instead of the rule of general applicability. *See* 415 ILCS 5/28.1(a) (2006); 35 Ill. Adm. Code 101.202, 104.400(a). In granting adjusted standards, the Board may impose conditions as may be necessary to accomplish the purposes of the Act. *See* 415 ILCS 5/28.1(a) (2006); 35 Ill. Adm. Code 104.428(a).

General Level of Justification Required

The regulations of general applicability at issue here do not specify a level of justification required to qualify for an adjusted standard. Accordingly, under Section 28.1(c) of the Act, a petitioner must demonstrate that:

1. Factors relating to that petitioner are substantially and significantly different from the factors relied upon by the Board in adopting the general regulation applicable to that petitioner;
2. The existence of those factors justifies an adjusted standard;
3. The requested standard will not result in environmental or health effects substantially and significantly more adverse than the effects considered by the Board in adopting the rule of general applicability; and
4. The adjusted standard is consistent with any applicable federal law. 415 ILCS 5/28.1(c) (2006); *see also* 35 Ill. Adm. Code 104.426(a).

Further, Section 28.1(a) of the Act (415 ILCS 5/28.1(a) (2006)) provides that the Board may grant an adjusted standard "for persons who can justify such an adjustment consistent with subsection (a) of Section 27 of this Act." Section 27(a) (415 ILCS 5/27(a) (2006)) is a

rulemaking provision that requires the Board to “take into account,” among other things, “the technical feasibility and economic reasonableness of measuring or reducing the particular type of pollution.”

**CURRENT APPLICABLE STANDARD &
BMTS’ PROPOSED ADJUSTED STANDARD**

The Board adopted the Illinois PIMW regulations at 35 Ill. Adm. Code 1422 in 1993, consistent with the mandate of the General Assembly in Public Act 87-752, effective January 1, 1992. Potentially Infectious Medical Waste (PIMW): Treatment, Storage, and Transfer Facilities and Transportation, Packaging, and Labeling (35 Ill. Adm. Code 1420, 1421, and 1422), R91-20 (June 17, 1993) (R91-20). The rules as adopted were based on recommendations of the Governor’s Medical Waste Tracking Study Group (Study Group), as that group’s consensus was proposed to the Board by the Agency. R91-20, slip op. at 1.

As the Board stated at the time, the fundamental provision of the rules was:

treatment to render waste non-PIMW. Because a waste that is PIMW may not be disposed of in Illinois, and because treatment is the process by which a waste ceases to be PIMW, the ultimate disposition of PIMW depends upon its being treated. R91-20, slip op. at 16.

At the time of the PIMW rules’ adoption, the prevalent sterilization technologies were incineration, steam sterilization, chemical disinfection and radiation. The rules require two tests of treatment efficiency, the first of which is called the Initial Efficacy Test (IET). The IET “requires that the manufacturer [of the treatment equipment or unit] assure that six types of ‘test’ microorganisms that are surrogates for pathogens be reduced to very low concentrations (a 6-log₁₀ reduction²) by the treatment process.” *Id.* at 17.

The PIMW rule at 35 Ill. Adm. Code Appendix A includes test procedures for verifying effective sterilization using an IET. Section 1422. Table B lists three indicator microorganisms to be used in the IET. BMTS asserts that two of these are not appropriate for validating dry heat systems like the Demolizer®. BMTS asserts that the other one (*Bacillus subtilis*, ATCC 19659) is no longer commercially available in a certified form. Pet. at 1-2.

BMTS requests an adjusted standard:

from the provisions of 35 IAC 1422. Table B (*sic*) recognizing *Bacillus atrophaeus* (ATCC 9372) as the most appropriate biological indicator organism for the validation of dry heat sterilization technologies. Am. Pet. at 3.

The specific language BMTS suggests is in the nature of rulemaking language:

² This means a 99.9999% reduction in microbial life.

amending Item 1 of Table B from “1. *Bacillus subtilis* (ATCC 19659)” to “1 *Bacillus subtilis* (ATCC 19659) or *Bacillus atrophaeus* (ATCC 9372).” *Id.*

PROCEDURAL HISTORY

BMTS filed its petition for adjusted standard on November 27, 2007. On December 12, 2007, BMTS filed the proof of timely publication of notice of the petition’s filing by advertisement in a newspaper of general circulation in the area likely to be affected by the proposed adjusted standard. *See* Section 28.1(d)(1) of the Act (415 ILCS 5/28.1(d)(1) (2006)) and Sections 104.408 and 104.410 of the Board’s procedural rules (35 Ill. Adm. Code 104.408, 104.410). BMTS filed certificates of publication with the Board stating that notice was published in both the *Chicago Tribune* and the *State Journal Register* on December 6, 2007. *See* 35 Ill. Adm. Code 104.410.

By order of December 20, 2007, the Board requested BMTS to file an amended petition by January 5, 2008 to clarify whether the substitute indicator organism is better referred to as *Bacillus subtilis* var. *niger* (ATCC 9372) or *Bacillus atrophaeus* (ATCC 9372)³. BMTS responded that *Bacillus atrophaeus* (ATCC 9372) is the preferred reference in an amended petition filed January 7, 2008. The amended petition was accompanied by a motion for leave to file *instanter*, which the Board grants.

The Agency timely filed a recommendation on December 28, 2007 and an amended recommendation on December 31, 2007 as required by 35 Ill. Adm. Code 104.416(a)). The Agency did not request a hearing on the petition, and recommends grant of the adjusted standard.

BMTS has waived hearing on the petition, and the Board has received no requests for a public hearing on the petition under 35 Ill. Adm. Code 104.420 in response to BMTS’ newspaper notice. Accordingly, no hearing has been held and the Board’s decision is based solely on the parties’ pleadings.

FACTUAL BACKGROUND AND PETITION CONTENTS

BMTS was incorporated in 2005 as a Colorado corporation. BMTS produces medical waste treatment devices that employ Demolizer® technology, which is based on a dry-heat treatment process that was developed in the mid-1990s. The user places medical wastes,

³ BMTS had previously filed a petition for variance seeking a change in the regulations. When BMTS did not file an amended petition specifying a compliance plan as requested in the Board’s order of July 20, 2007, the Board dismissed the petition. Biomedical Technology Solutions, Inc. v. IEPA, PCB 07-149 (orders of July 20, 2007 and Sept. 20, 2007). BMTS’ variance petition in PCB 07-149 requested substitution of *Bacillus atrophaeus* (ATCC 9372), whereas the instant adjusted standard petition requests substitution of *Bacillus subtilis* var. *niger* (ATCC 9372). But, BMTS also states that *Bacillus subtilis* var. *niger* was formally reclassified as *Bacillus atrophaeus* in the International Journal of Systematic and Evolutionary Microbiology (2001), 51, 35-37. Pet. at 11. The Board requested clarification of the discrepancy in its December 20, 2007 order, resulting in use of *Bacillus atrophaeus* (ATCC 9372) throughout this opinion and order.

including "sharps," into the Demolizer® device, which is approximately the size of the common microwave. Through the course of a treatment cycle, the waste is sterilized and "rendered into a non-recognizable solid waste that can then be disposed of as any other refuse." The technology is formally approved or meets statutory requirements in 46 states. The technology heats one gallon of medical waste to a minimum treatment temperature of 350°F for a minimum of 90 minutes. BMTS reports that the temperature profile completely destroys sharps waste through a slow-melting of the plastic components of used syringes. The resulting melted mass is contained in the bottom of the metal collector for final disposal as "ordinary solid waste." Pet. at 2.

BMTS' target market is businesses that generate relatively low volumes of medical waste such as nursing homes, medical, dental and veterinary offices, and pharmacies, which can use BMTS devices on-site as a safe and efficient method of treating and disposing of their waste materials. BMTS states that the Demolizer® technology has demonstrated broad-scale efficacy under these treatment conditions through studies at Stanford University, Kansas State University, and various private laboratories. BMTS asserts it has customers in almost every state and has begun marketing the technology worldwide, and that its product meets regulatory requirements in 46 states. *Id.*

In order to market its device in Illinois, BMTS must demonstrate compliance with the Board's PIMW rules. BMTS reports that the sole indicator organism specified in the rule that is applicable to its process is *Bacillus subtilis* (ATCC 19659). BMTS states that ATCC 19659 is not commercially available in a certified form, and the procedure for growing and certifying ATCC 19659 to the same standards achieved using the most appropriate *Bacillus subtilis* certified microorganism could take close to two and a half years and cost upwards of \$320,000. Pet. at 3.

BMTS' suggested alternative to ATCC 19659 is a variant of the same species, ATCC 9372 *Bacillus subtilis* var. *niger*, also known as *Bacillus atrophaeus*. BMTS states that ATCC 9372 "exhibits superior dry heat resistance and can be distinguished from the generic *Bacillus subtilis* primarily through differences in color or pigmentation response to certain media. Pet at 1. Moreover, BMTS explains, "over 99.8 % of their genetic material is *identical*—meaning that, but for their color, the [two] indicators are indistinguishable." Pet. at 8, emphasis in original.

BMTS states that ATCC 9372 is commercially available in a certified form and is the scientifically recognized standard in 46 states as well as the international community for the validation of dry heat sterilization processes due to its superior growth and heat resistance properties. BMTS relates that *Bacillus atrophaeus* is commonly used for the validation of chemical disinfectants and is, therefore, most appropriate for the validation of alternative technologies employing a chemical sterilization agent. According to BMTS, *Bacillus subtilis* is not recognized by international standards organizations or in the scientific literature for the validation of dry heat sterilization technologies.

BMTS relates that *Bacillus atrophaeus* exhibits enhanced resistance in dry heat applications compared to a generic *Bacillus subtilis* organism (such as that specified in the Board's rules. See Pet. at 4, citing Group Exhibit J,3 Gurney, T.R. & Quesnel, L.B., *Thermal*

Activation and Dry-heat Inactivation of Spores of Bacillus subtilis MD2 and Bacillus subtilis var. niger, J. APPLIED BACTERIOLOGY, 48, 231-247 (1980).

BMTS contends that Illinois is the only of 46 states that would require BMTS to demonstrate the effectiveness of its devices by use of *Bacillus subtilis* (ATCC 19659) rather than *Bacillus atrophaeus* (ATCC 9372). Pet. at 5. BMTS reports that various international standards organizations have specified ATCC 9372 as “the preferred biological indicatory organism for dry-heat processes”, include the US Pharmacopoeia, the Food and Drug Administration, the British Pharmacopoeia Commission, the European Pharmacopoeia Commission, the Japanese Pharmacopoeia, the International Organization for Standardization, and ANSI. *Id.* at 4-5.

Compliance Efforts and Alternatives

BMTS has already performed an efficacy test of its equipment using *Bacillus atrophaeus*. In 2006, BMTS commissioned Dr. James Marsden, Regent's Distinguished Professor at Kansas State University (KSU), to conduct an initial efficacy test for its updated Demolizer® technology that could be used to secure regulatory approval both in the United States and internationally (the KSU Efficacy Test). BMTS has submitted these results to various governmental entities, which have approved their results. Pet. at 12 and Exh. I.

BMTS submitted the results of the KSU Efficacy Test to the Agency in mid-October 2006. On January 5, 2007, the Agency formally determined that the KSU Efficacy Test did not meet the IET requirements of the PIMW rules. The petition details various exchanges of information between BMTS and the Agency throughout 2007. But, the Agency continued to believe that IET requirements had not been met. See Pet. at 12-15, and Exhibits cited therein.

After learning of the Agency's position, BMTS requested that KSU's Dr. Marsden prepare an estimate to repeat the KSU Efficacy Test using *Bacillus subtilis* (ATCC 19659) to the same quality standards as attained in the original KSU Efficacy Study. Dr. Marsden informed BMTS that, in order to grow a custom indicator and ensure comparable quality standards to the previously conducted study using a certified carrier, the study would require two major phases. The first phase would involve growing a culture population of a custom indicator compliant with the PIMW rules and certifying its resistance properties through exhaustive D-value⁴ studies. Dr. Marsden would use standard protocols for validating the resistance of the culture similar to those used throughout the industry. This study could need to be repeated several times until a population is grown to the standards comparable to the *Bacillus atrophaeus* indicator those obtainable from certified manufactures.

Dr. Marsden provided an estimate of a minimum of \$60,000 for a single D-value evaluation of a population. BMTS believes it is very possible that repeated trials could result in a total cost approaching \$250,000 to properly certify the population with a total time frame of up to two years. BMTS emphasizes that these estimates are phase-one costs only.

⁴ An organism's D-value is the treatment time required for 90% deactivation.

Once a custom *Bacillus subtilis* indicator population had been grown and certified, the second phase could begin, which involves repeating the Demolizer® efficacy study using appropriate replicates, load conditions, etc. This requires a minimum of 2-4 months to coordinate and report the study. Upon completion of both phases, validation results could be obtained. Dr. Marsden's cost estimate for phase two of the validation study using ATCC 19659 is \$40,000. In addition to these costs, BMTS would incur direct costs totaling more than \$30,000, which includes the cost of three dedicated systems and the cost of BMTS staff time to be on-site at Kansas State University to facilitate the trial.

BMTS concludes that the total cost for repeating the efficacy study using a custom indicator is estimated to be between \$130,000 and \$320,000 dollars and could take up to two and a half years to complete. Pet. at 26-27 and Exhibit I.

Substantially Different Factors

BMTS asserts that various factors relating to it are substantially and significantly different from the factors relied upon by the Board in adopting the R91-20 PIMW rules in 1993. BMTS states that, at that time, infectious waste treatment technologies available both domestically and internationally primarily consisted of autoclave or steam sterilization, chemical disinfection, and radiation. At the time the rules were adopted, the Demolizer® technology had not even been formally introduced. Moreover, the scientific consensus and published standards for the validation of dry heat sterilization technologies both domestically and internationally "converged on the selection of [*Bacillus atrophaeus*] in the mid to late 1990s as the most appropriate indicator organism for the validation of such technologies.

Adjusted Standard Justified

BMTS points out that the possible need for adjusted standards from the PIMW rules was pointed out by the Board in its second notice opinion and order in R 91-20. In its discussion of Section 1422.123 entitled "Treatment Units", the Board specifically supported the concept articulated by the Study Group and the Agency that the rule's provisions "allow easy consideration for new technologies that do not fit the definition of chemical, thermal, or irradiation treatment. Potentially Infectious Medical Waste (PIMW): Treatment, Storage, and Transfer Facilities and Transportation, Packaging, and Labeling (35 Ill. Adm. Code 1420, 1421, and 1422), R 91-20, slip op. at 19 (second notice Mar. 23, 1993).

The Board acknowledged the Agency's concerns about the potential administrative burden of adjusted standards proceedings. But, the Board also specifically emphasized that adjusted standards relief need not be site-specific in nature, but could also be technology-specific. *Id.* at 20.

BMTS believes that this, in addition to all of the other information supplied in support of its petition, justifies the grant of the relief it requests by way of adjusted standard.

Impact on Environment

BMTS contends that its requested adjusted standard will not result in environmental or health effects substantially or significantly more adverse than the effects considered by the Board in adopting the rule of general applicability. BMTS argues the scientific evidence suggests that its use of *Bacillus atrophaeus* (ATCC 9372) rather than *Bacillus subtilis* (ATCC 19659) will be protective of the environment. Further, BMTS states that the former indicator “poses a more difficult challenge for the Demolizer® technology” than does the latter, and that BMTS has demonstrated that the Demolizer® technology delivers a minimum 6-log₁₀ reduction of the *Bacillus atrophaeus* indicator consistent with the PIMW disinfection standard. Pet. at 27.

Consistency with Federal Law

BMTS argues that any adjusted standard would be consistent with federal law, as PIMW treatment and approval of treatment technologies are not regulated at the federal level. However, BMTS again notes that the use of *Bacillus atrophaeus* (ATCC 9372) as the preferred indicator for validation of dry heat sterilization has gained federal and international approval. Pet. at 28.

AGENCY AMENDED RECOMMENDATION

In summary, the Agency recommends support of adjusted standard. The Agency states that it does not support relief from 35 Ill. Adm. Code Part 122 generally, but instead suggests that the “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).” Am. Rec. at 3.

The Agency disagrees with some of BMTS’ contentions. The Agency suggests that PIMW treated by the Demolizer® technology would still be an “industrial process waste” or a “special waste” under Board rules, and so could not be treated like any other “solid waste” or “refuse” as BMTS states. *Id.*

The Agency suggests that BMTS’ assertions that the Demolizer® technology “meets statutory requirements in 46 states” is “suspect” and may not be entirely accurate. The Agency does agree, though, that the technology is formally approved in 22 states, and approval is in process elsewhere. *Id.* Similarly, the Agency questions whether it is entirely accurate to say that “46 states scientifically recognize ATCC 9372”, when “23 states do not review technologies”. *Id.* at 2-3. The Agency also took issue with petitioner’s assertion that “the Agency has agreed to recommend that it grant this Petition”, stating that the Agency preferred to make its own conclusions and recommendations. *Id.* at 4, quoting Pet. at 15.

As to compliance efforts and alternatives, the Agency does not disagree with BMTS’ assertions concerning the scientific validity of use of *Bacillus atrophaeus* (ATCC 9372). However, the Agency suggests that any “arbitrary or unreasonable hardship” BMTS asserts is largely of its own making. The Agency points out that:

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. Illinois regulations relative to which strain of indicator spore to used [sic] were enacted [in 1993] following a long regulatory process. . . .

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 IET 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. Am. Rec. at 6.

The Agency does not take issue with BMTS' statements concerning environmental impact, justification for the adjusted standard, or consistency with federal law. *Id.* at 8-9. The Agency Amended Recommendation states, in summary:

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 . . . from the requirement that *Bacillus 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. Am. Rec. at 9.

BOARD ANALYSIS

Based on the record, the Board finds that BMTS has justified grant of the adjusted standard from the PIMW rules it requests. When the Board adopted the PIMW rules in 1993, the Board incorporated the most up-to-date scientific information available as identified by the Agency, the Study Group, and other participants in the rulemaking. As suggested by BMTS, all concerned were highly conscious that technology was evolving and that adjustment or updating of the rules would be necessary at some point. The Board's goal was to "allow easy consideration for new technologies". *See, e.g., Potentially Infectious Medical Waste (PIMW): Treatment, Storage, and Transfer Facilities and Transportation, Packaging, and Labeling* (35 Ill. Adm. Code 1420, 1421, and 1422), R91-20, slip op. at 19 (second notice Mar. 23, 1993). While in many respects updating of the rule text itself is preferable, the Board clearly contemplated the need to issue technology-specific adjusted standards from the PIMW rules.

BMTS contends, and the Agency does not disagree, that the Demolizer® dry heat sterilization technology had not even been formally introduced in 1993 when the rules were adopted. The R 91-20 proceeding did not consider standards for the validation of dry heat sterilization technologies. The record in this proceeding demonstrates that scientific consensus has been reached that *Bacillus atrophaeus* (ATCC 9372) is the most appropriate indicator organism for the validation of such technologies. However, this consensus was not reached until the mid-to-late 1990's, well after the PIMW rulemaking was concluded. The Board finds that the “factors relating to the petitioner are substantially and significantly different than the factors relied upon by the Board in adopting the general regulation applicable to the petitioner.” 415 ILCS 5/28.1(c)(1) and (2) (2006).

Based on much of the same record information, the Board also concludes that the granting of an adjusted standard will have no adverse environmental impact, and that use of the suggested alternative indicator organism is appropriate for use in testing the Demolizer®. 415 ILCS 5/28.1(c)(3) (2006). The Board finds that federal law is no bar to granting the requested relief, as there are no federal regulations in this area. *See* 415 ILCS 5/28.1(c)(4) (2006).

For all of the reasons described here, the Board finds that BMTS has provided sufficient justification under Section 28.1 of the Act for an adjusted standard. 415 ILCS 5/28.1 (2006). As to the economic and technical justification for the proposed adjusted standard,⁵ the Board finds that use of the indicator organism proposed is scientifically justified, and preferable for validation of the efficiency of the Demolizer® dry heat sterilization technology to use of the organisms specified in the rule. BMTS has conducted one test using its preferred organism, and seeks to avoid costs of a re-test using a more expensive, and less appropriate one. Much of the Agency's discussion concerning BMTS' petition concerns whether any economic hardship caused by a need to re-test is self-imposed. This concern would be of great weight were this a variance proceeding, where the Board must determine whether immediate compliance with the rule would “impose an arbitrary or unreasonable hardship.” *See* 415 ILCS 5/35(a) (2006). The “self-imposed hardship” consideration is of almost no weight in the circumstances of this particular adjusted standard proceeding.

Since the PIMW rules were designed to “allow easy consideration for new technologies”, the Board places the greatest weight on BMTS' scientific proofs in finding that an adjusted standard is justified. Scientific consensus favors use of the *Bacillus atrophaeus* (ATCC 9372) indicator organism for demonstration of the effectiveness of dry heat sterilization in an Initial Efficacy Test to that of the *Bacillus subtilis* (ATCC 19659) listed in the Board's PIMW rules located at 35 Ill. Adm. Code Section 1422.Appendix A, Table B(1). The Board grants BTMS an

⁵Again, Section 28.1(a) of the Act (415 ILCS 5/28.1(a) (2006)) provides that the Board may grant an adjusted standard “for persons who can justify such an adjustment consistent with subsection (a) of Section 27 of this Act.” Section 27(a) (415 ILCS 5/27(a) (2006)) is a rulemaking provision that requires the Board to “take into account,” among other things, “the technical feasibility and economic reasonableness of measuring or reducing the particular type of pollution.”

adjusted standard upon the condition that an appropriate test is performed using *Bacillus atrophaeus* (ATCC 9372) and the results of such test comply with the requirements of this Part. Am. Rec. at 9. The Board's language is similar, but not identical, to that suggested by the Agency.

This opinion constitutes the Board's findings of fact and conclusions of law.

ORDER

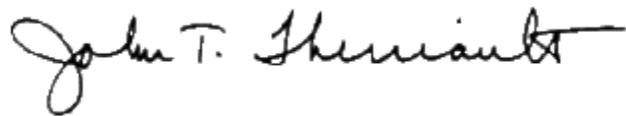
The Board grants an adjusted standards to Biomedical Technology Solutions, Inc. (BMTS) from the requirement that BMTS use any of the indicator organisms listed at 35 Ill. Adm. Code Section 1422.Appendix A, Table B(1) when performing an Initial Efficacy Test of its Demolizer® dry heat sterilization technology. In lieu of the listed organisms, BMTS may use only *Bacillus atrophaeus* (ATCC 9372). BMTS must comply with all other requirements of 35 Ill. Adm. Code 1422.

IT IS SO ORDERED.

Section 41(a) of the Environmental Protection Act provides that final Board orders may be appealed directly to the Illinois Appellate Court within 35 days after the Board serves the order. 415 ILCS 5/41(a) (2006); *see also* 35 Ill. Adm. Code 101.300(d)(2), 101.906, 102.706. Illinois Supreme Court Rule 335 establishes filing requirements that apply when the Illinois Appellate Court, by statute, directly reviews administrative orders. 172 Ill. 2d R. 335. The Board's procedural rules provide that motions for the Board to reconsider or modify its final orders may be filed with the Board within 35 days after the order is received. 35 Ill. Adm. Code 101.520; *see also* 35 Ill. Adm. Code 101.902, 102.700, 102.702.

IT IS SO ORDERED.

I, John Therriault, Assistant Clerk of the Illinois Pollution Control Board, certify that the Board adopted the above opinion and order on April 3, 2008, by a vote of 4-0.



John Therriault, Assistant Clerk
Illinois Pollution Control Board