

Report #000401RA

May 3, 2001

The Effects of Transient Conditions During Shipping on SGMStrip™ Biological Indicators Containing *Bacillus stearothermophilus* Spores

I. Introduction:

Customers and regulatory agencies are frequently asking manufacturers for data to document the effects of transient conditions during shipment of biological indicators.

This report documents the effects of shipping on SGM biological indicators from the U.S. to Europe and back. Questions have also been asked regarding the length of time between the exposure of biological indicators and culturing. Included in this study were unexposed biological indicators as well as biological indicators exposed to fraction negative cycles in an AAMI BIER vessel. A similar set of unexposed and exposed biological indicators were held at SGM under controlled environmental conditions. Upon completion of the shipping portion of this study all units were tested.

The SGMStrip biological indicators containing *Bacillus stearothermophilus* spores were used in this study. SGM Biotech recommends that these biological indicators be stored at controlled room temperature. Controlled room temperature is defined in the USP 24, page 11 as **“A temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° to 86°F) that are experienced in pharmacies, hospitals and warehouses...”** **“An article for which storage at controlled room temperature is directed may, alternatively, be stored in a cool place, unless otherwise specified...on the label. Cool is defined as “...any temperature between 8° and 15°C (46° to 59°F)”**. The USP does not address any particular relative humidity in these storage environments. SGM recommends a range of 20% to 70% RH.

The USP also states in the Guide to General Chapters Microbiological tests/<55> Biological Indicators, page 1818 that **“...after completion of the sterilizing procedure... and within a noted time not greater than 4 hours, aseptically remove and add each strip to 10 to 30 ml of Soybean Casein Digest medium...”**

The general chapters are for information only and are not regulatory in nature. The issue still remains - will a delay in culturing of biological indicators exposed to fractional sterilization cycles cause an adverse condition that prevents the recovery of these injured spores?

This study was undertaken to monitor transient conditions of exposed and unexposed SGMStrip biological indicators. Three replicate shipments were sent to Sweden and returned to Bozeman, Montana. TinytagPlus® Type TGP-1500 humidity and

temperature data recorders were packaged with the biological indicators to continuously monitor environmental conditions during transit. Upon receipt at SGM's laboratory the population and D-value data of these shipped samples and samples held in SGM's laboratory were compared.

Three lots of SGMStrip biological indicators containing *B. stearothermophilus* spores were used in this study, one for each shipment. Each lot was manufactured from a different spore crop.

II. Methods and Materials:

The following equipment and supplies were used:

- 3 lots of SGMStrip-Steam (*Bacillus stearothermophilus*)
 - 394 strips of Bst 050499/S2-1
 - 404 strips of Bst 012800/S2-1
 - 404 strips of Bst 022400/S2-1
- Joslyn Sterilizer Corp. Steam B.I.E.R.
- 3 Tinytag^{Plus}® Type TGP-1500 Humidity/Temperature Data Recorders (Provided by Pharmacia-Sweden)
 - Serial Number 139342
 - Serial Number 136855
 - Serial Number 136868
- Tryptic® Soy Broth (Difco)
- Tryptic® Soy Agar (Difco)

III. Procedure:

1. Three different lots of *Bacillus stearothermophilus* SGMStrip biological indicators were used. Population assays and D_{121} -values of the strips were performed at the beginning of the study for each of the three lots.
2. To determine the effects of transient conditions during shipment of SGMStrips, 160 unexposed strips of each of the three lots were divided into two groups: shipped units and units stored at SGM as the control group.

An additional 120-140 strips of each of the three lots were exposed in a steam BIER vessel at 121°C, employing the same exposure times that were used initially to determine the D-values for certification of the lots. After the strips were exposed, half of each lot was stored at SGM and the other half of each lot was used in the shipping portion of the study. This phase of the study simulated test strips being sent to an off-site laboratory for culturing. Ten (10)-twenty (20) strips from each lot were included in each group to serve as positive controls.

3. The strips were packaged into polyethylene bags. Sample sets included unexposed strips (standard product) and strips that were exposed to fractional cycles. Each lot was packaged for shipment with a Tinytag*Plus*® data recorder. For each shipment, a duplicate box containing a similar set of strips was retained at SGM and held at controlled room temperature. The stored strips served as controls. Each lot was sent on three separate days by expedited UPS courier to Miclev, the SGM distributor in Sweden. Miclev forwarded the packages to Pharmacia-Sweden. Pharmacia-Sweden downloaded the data from the Tinytag*Plus*® data recorders and then returned the packages to SGM by expedited UPS courier. The Tinytag*Plus*® data recorders were then sent back to Pharmacia-Sweden who again downloaded the temperature and humidity history of the shipments from the data recorders. Receiving and shipping dates were recorded on the Receiving/Shipping Record.
4. After the strips were received at SGM's laboratory, they were stored at controlled room temperature until they could be processed. Populations and D-value determinations of the shipped and stored (control) strips were performed. The D-values on the shipped unexposed strips employed the same time exposures used to determine the initial D-values.

IV. Results and Discussions:

A. **Transient Environmental Conditions During Shipping From the U.S. to Europe and Back to the U.S.**

1. Shipping and Receiving Dates:

The shipping and receiving dates of each shipment are presented in Table 1. The Tinytag*Plus*® data recorder used in Shipment 2 malfunctioned for the first half of the shipment. The data recorder was repaired when received by Pharmacia. The temperature and humidity data starting on August 10, 2000, was used in this study along with the data obtained from the second shipment of sample set two. Therefore the samples noted as Shipment 2, were exposed to two complete shipment cycles.

Table 1: Shipping and Receiving Dates

Shipped/Received	Shipment 1	Shipment 2		Shipment 3
		First Time	Second Time	
SGM Biotech, Inc. -	00-07-14	00-07-17	00-08-18	00-07-18
Miclev +	00-07-25	00-07-24	00-08-22	00-07-24
Miclev -	00-07-27	00-07-26	00-08-22	00-07-25
Pharmacia +	00-08-10	00-08-10	00-08-24	00-08-10
Pharmacia -	00-08-11	00-08-10	00-08-25	00-08-14
SGM Biotech, Inc. +	00-08-15	00-08-15	00-08-28	00-08-21

- Shipped by + Received by

2. Number of Days in Transit:

The number of days the shipment was in transit and the number of days that it was stored by SGM, Miclev, and Pharmacia is listed in Table 2. The average time for a shipment being sent from SGM to Miclev was 8 days, Miclev to Pharmacia took an average of 12.5 days, and Pharmacia to SGM was an average of 5.5 days. The total transit time for Shipment 1 was 33 days and Shipment 3 was 35 days. Shipment 2 was in transit a total of 43 days (First Shipment 2 plus Second Shipment 2), but only 18 of those days have temperature/humidity data due to the data recorder malfunctioning for the first half of Shipment 2.

Table 2: Time of Shipments in Transit

Shipped/ Received	Shipment 1	Shipment 2		Shipment 3	Average Time
		First Time	Second Time		
SGM to Miclev	12 days	8 days	<i>Held 2 days by SGM</i> 5 days	7 days	8 days
Miclev to Pharmacia	<i>Held 1 day by Miclev</i> 15 days	<i>Held 1 day by Miclev</i> 16 days	2 days	17 days	12.5 days
Pharmacia to SGM	5 days	5 days	4 days	<i>Held 3 days by Pharmacia</i> 8 days	5.5 days
Total Days in Transit	33 days	30 days	13 days	35 days	27.75 days

3. Temperature During Transit:

Average temperatures for all three shipments were within the defined controlled room temperature range of 20°-25°C (Table 3). Shipment 1 had an average temperature of 22.4°C, Shipment 2 was 23.4°C, and the average temperature of Shipment 3 was 22.5°C. The information obtained from the TinytagPlus® data recorders showed that the temperatures the strips were exposed to during transit ranged from a high of 42.02°C for Shipment 1 to a low of 13.95°C for Shipment 2. These temperatures are outside the defined controlled room temperature range.

For a graphical representation of the temperature data obtained from the TinytagPlus® data recorders in each shipment, see Figures 1 through 6.

Table 3: Temperature During Transit

Shipment	Mean Kinetic Temperature	Minimum Temperature	Maximum Temperature
1	22.4°C	15.38°C	42.02°C
2	23.4°C	13.95°C	37.50°C
3	22.5°C	17.42°C	31.41°C

4. Time and Temperature Excursions During Transit:

Of the three shipments, Shipment 2 experienced the longest time out of defined controlled room temperature (Table 4). The temperature was above the excursion range of 15°-30°C for more than 13 hours, and in cool temperatures (8° to 15°C) for 56 minutes. Shipment 1 experienced the highest temperature of 12.02°C above controlled room temperature. Only Shipment 2 experienced cool conditions with a temperature of 1.05°C below the allowed room temperature excursion range.

Table 4: Transient Temperature and Time Above and Below Controlled Room Temperature

Shipment	Degrees Above Controlled Room Temperature (30.00°C and Higher)	Time Above Controlled Room Temperature	Degrees in Defined Cool Temperature (15.00°C-8.00°C)	Time in Defined Cool Temperature
1	+12.02°C	504 min. (8.40 hrs.)	--	0 min.
2	+7.50°C	826 min. (13.77 hrs.)	-1.05°C	56 min.
3	+1.41°C	330 min. (5.50 hrs.)	--	0 min

5. Humidity Levels During Transit:

Data from the Tinytag*Plus*® revealed the average humidity of the three shipments was within SGM's recommended range of 20% to 70% (Table 5). Shipment 1 had an average humidity of 50.4%, Shipment 2 was 41.9%, and Shipment 3 was 48.3%. The humidity ranged from a high of 78.39% (Shipment 2) to a low of 12.06% (Shipment 1).

For a graphical representation of the humidity data obtained from the Tinytag*Plus*® data recorders in each shipment, see Figures 1 through 6.

Table 5: Humidity During Shipping

Shipment	Mean Humidity	Minimum Humidity	Maximum Humidity
1	50.4%	12.06%	78.20%
2	41.9%	22.44%	78.39%
3	48.3%	22.95%	74.82%

6. Time and Humidity Excursions During Transit:

Shipment 1 experienced the longest time (31.62 hours) and the lowest humidity (7.94%) below the recommended humidity range of 20% to 70%.

Shipment 2 experienced the longest time (3.15 hours) and highest humidity (8.39%) above the recommended humidity range.

Shipment 3 experienced only 12 minutes above the recommended humidity values.

High humidity is not detrimental to the SGMStrip provided it does not become wet. Low humidity helps in preserving the quality of the spores.

Table 6: Transient Relative Humidity Levels and Time Above and Below Recommended Storage Conditions

Shipment	Percentage Above Recommended Humidity (70.00% and Higher)	Time Above Recommended Humidity	Percentage Below Recommended Humidity (20.00% and Lower)	Time Below Recommended Humidity
1	+8.20%	105 min. (1.75 hrs.)	-7.94%	217 min. (31.62 hrs.)
2	+8.39%	189 min. (3.15 hrs.)	--	0 min.
3	+4.82%	12 min. (0.20 hrs.)	--	0 min.

A graphical representation of the temperature and humidity data obtained from the Tinytag*Plus*® data recorders in each shipment is shown in Figures 1 through 6.

B. Biological Results

1. Elapsed Time in Testing Unexposed Units:

Total transit time for Shipment 1 was 33 days, Shipment 2 was 43 days, and Shipment 3 was 35 days (Table 7). Population determination and D-value testing of the unexposed strips could not be performed immediately upon return to SGM due to the number of units to be tested. To perform final population determinations after return of the samples required eleven (11) days for Shipment 1, 28 days for Shipment 2, and 29 days for Shipment 3.

Final D-value testing for the three shipments was completed in 21 days after the return of the samples. The total time between initial population testing and testing after shipping was 122 days for Shipment 1, 139 days for Shipment 2, and 140 days for Shipment 3. The total time between the initial D-value testing and testing after shipping was 112 days for all three shipments.

Table 7: Time Between Initial Testing, Final Testing, and Transit Time of Unexposed SGMStrip Biological Indicators

Shipment	Lot Number	Time From Initial Population Determination to Final Determination	Time From Initial D-Value Testing to Final Testing	Total Transit Time	Time Stored at SGM Before Population Determination	Time Held at SGM Before D-value Testing
1	Bst-050499/S2-1	122 days	112 days	33 days	11 days	21 days
2	Bst-012800/S2-1	139 days	112 days	43 days	28 days	21 days
3	Bst-022400/S2-1	140 days	112 days	35 days	29 days	21 days

2. Elapsed Time in Testing Exposed Units:

The exposed units could not be cultured immediately after the return of the samples due to the number of units to be tested. Shipment 1 was cultured within two days after receipt. Shipment 2 and 3 were cultured 24 days after receipt.

The time between exposing the units to fractional steam exposures, shipping, and culturing was 55 days for Shipment 1, and 71 days for Shipments 2 and 3 (Table 8). This is significantly longer than the four (4) hours recommended by the USP.

Table 8: Time Between Fractional Steam Exposures to Culturing and Transit Time of SGMStrip Biological Indicators

Shipment	Lot Number	Time From Fractional Steam Exposures to Culturing	Total Time in Transit	Time Held at SGM Before Culturing
1	Bst-052499/S2-1	55 days	33 days	2 days
2	Bst-012800/S2-1	71 days	43 days	24 days
3	Bst-022400/S2-1	71 days	35 days	24 days

3. D-value Results of Unexposed Strips:

No significant difference was observed in the D-value data between unexposed units before shipping, after shipping, and units stored (Table 9). The D-value of the units in Shipment 1 was 2.9 minutes initially, 3.0 minutes for shipped, and 2.9 minutes for stored. In Shipment 2, the D-value was 2.7 minutes initially, 2.7 minutes for shipped, and 2.7 minutes for stored. The D-value in Shipment 3 was 2.5 minutes initially, 2.5 minutes for shipped, and 2.4 minutes for stored. The only changes in D-value were in shipped units from Shipment 1 with a +3% difference from initial testing, and stored units in Shipment 3 with a -4% difference from initial testing.

According to USP 24 the acceptable range in D-value reproducibility is $\pm 20\%$ of the labeled claim. SGM normally expects less than $\pm 10\%$ D-value variance between individual tests performed simultaneously. This variation is most likely due to differences in laboratory technicians, equipment, and media.

Table 9: D-value Results for Unexposed Strips

Shipment	Lot Number	Initial D-value Attained Less Than 4hrs. After Exposure	D-value of Shipped Unexposed Units	D-value of SGM Stored Units
1	Bst-050499/S2-1	2.9	3.0 (+3% difference)	2.9 (+0% difference)
2	Bst-012800/S2-1	2.7	2.7 (+0% difference)	2.7 (+0% difference)
3	Bst-022400/S2-1	2.5	2.5 (+0% difference)	2.4 (-4% difference)

4. D-value Results of Exposed Strips:

No significant difference was seen in the D-value data of the exposed strips before shipping, after shipping, and from those that were stored (Table 10). The D-value of the strips in Shipment 1 was 2.9 minutes initially, 2.8 minutes for shipped units, and 2.5

minutes for stored units. In Shipment 2, the D-value of the strips was 2.7 minutes initially, 2.3 minutes for shipped units, and 2.6 minutes for stored units. The D-value of the strips in Shipment 3 was 2.5 minutes initially, 2.3 minutes for shipped units, and 2.3 minutes for stored units.

The difference from initial D-value testing in shipped units from Shipment 1 was -3% and stored units was -14% . The difference from initial D-value testing in shipped units from Shipment 2 was -15% and stored units was -4% . The difference from initial D-value testing in shipped units from Shipment 3 and stored units was -8% .

In this study the D-values of exposed strips are lower than the D-values of unexposed strips. This indicates that culturing within four (4) hours of exposure recovers more injured spores, but a delay in culturing strips (up to 71 days - Table 8) still provides D-value reproducibility within 20%.

Table 10: D-value Results for Exposed Strips

Shipment	Lot Number	Initial D-value Attained Less Than 4hrs. After Exposure	D-value of Shipped Exposed Units	D-value of SGM Stored Units
1	Bst-050499/S2-1	2.9	2.8 (-3% difference)	2.5 (-14% difference)
2	Bst-012800/S2-1	2.7	2.3 (-15% difference)	2.6 (-4% difference)
3	Bst-022400/S2-1	2.5	2.3 (-8% difference)	2.3 (-8% difference)

The recovery data for the D-value results of exposed strips show little difference between the results from initial testing, testing after shipping, and testing after storage (Table 11).

In Shipment 1, total kill was achieved in 20 minutes for initial, shipped and stored units. In Shipments 2 and 3 total kill was achieved in 16 minutes for initial, shipped and stored units. The only changes in survivor time occurred in shipped units of Shipment 2 and Shipment 3, which change from ten (10) units to nine (9) units.

The only consistent changes in the recovery data of units that were shipped and stored, versus the initial recovery testing data were in the fractional times between the total survivor and the total kill times. These fractional times had less samples demonstrating surviving spores than the initial test fractional value. However,

these differences were not great enough to influence the D-value calculation by more than 15%. The changes in the recovery data still provided D-value reproducibility within 20%.

Table 11: Recovery Data for D-value Results of Exposed Strips

	Initial Test		Shipped		Stored at SGM	
Shipment 1	U (Min)	#Killed	U (Min)	#Killed	U (Min)	#Killed
Bst 0050499/S2-1	10	0	10	0	10	0
	12	1	12	1	12	1
	14	2	14	0	14	4
	16	4	16	6	16	9
	18	6	18	7	18	10
	20	10	20	10	20	10
121°C D-value	D-value: 2.9 min.		D-value: 2.8 min.		D-value: 2.5 min.	
Shipment 2	U (Min)	#Killed	U (min)	#Killed	U (Min)	#Killed
Bst 012800/S2-1	10	0	10	2	10	0
	11	0	11	0	11	0
	12	0	12	1	12	1
	13	2	13	5	13	3
	14	1	14	7	14	4
	15	2	15	10	15	7
	16	10	16	10	16	10
121°C D-value	D-value: 2.7 min.		D-value: 2.3 min.		D-value: 2.6 min.	
Shipment 3	U (Min)	#Killed	U (Min)	#Killed	U (Min)	#Killed
Bst 022400/S2-1	10	0	10	1	10	0
	11	0	11	2	11	1
	12	2	12	5	12	3
	13	3	13	4	13	8
	14	8	14	10	14	8
	15	7	15	10	15	10
	16	10	16	10	16	10
121°C D-value	D-value: 2.5 min.		D-value: 2.3 min.		D-value: 2.3 min.	

5. Population Data:

Little difference was noted when comparing population data of the strips before shipping, after shipping, and from those that were stored (Table 12). The population in Shipment 1 was 2.4×10^5 /strip initially, 1.7×10^5 /strip for shipped, and 1.6×10^5 /strip for stored. In Shipment 2, the population was 1.8×10^5 /strip initially, 1.7×10^5 /strip for shipped and 1.4×10^5 /strip for stored. The population in Shipment 3 was 1.5×10^5 /strip initially, 1.5×10^5 /strip for shipped, and 2.4×10^5 /strip for stored.

The difference in Shipment 1 from initial population testing in shipped units was -29% and stored units was -33% . The difference in Shipment 2 from initial population testing in shipped units was -6% and stored units was -22% . The difference in Shipment 3 from initial population testing in shipped units was 0% and stored units was $+60\%$.

The acceptable range in population reproducibility for a biological indicator is -50% and $+300\%$ of the labeled claim. This study's average in population variance was 25% . SGM normally expects a $\pm 30\%$ population variance between individual tests performed simultaneously by SGM technicians. These variations are most likely due to differences in laboratory technicians, equipment, and media.

Table 12: Population Results for Strips

Shipment	Lot Number	Initial Population	Population of Shipped Units	Population of SGM Stored Units
1	Bst-050499/S2-1	2.4×10^5	1.7×10^5 (-29% difference)	1.6×10^5 (-33% difference)
2	Bst-012800/S2-1	1.8×10^5	1.7×10^5 (-6% difference)	1.4×10^5 (-22% difference)
3	Bst-022400/S2-1	1.5×10^5	1.5×10^5 (0% difference)	2.4×10^5 ($+60\%$ difference)

V. Conclusions:

1. During shipment, unexposed and exposed SGMStrip biological indicators experienced transient excursions of temperature and humidity outside of the manufacturer's recommended storage conditions.
 - 1.1. Shipment 1 was above the USP controlled room temperature limit for 8.4 hours during the 33 days of transit or 1% of the time.
 - 1.2. Shipment 2 was above the USP controlled room temperature limit for 13.77 hours during the 43 days of transit or 1.3% of the time.
 - 1.3. Shipment 3 was above the USP controlled room temperature limit for 5.5 hours during the 35 days of transit or 0.6% of the time.
2. The mean kinetic temperatures ranged between 22.4°C and 23.4°C . The USP states the mean kinetic temperature for controlled room temperature should not exceed 25°C .
3. The population ranged from -33% to $+60\%$. SGM normally expects a $\pm 30\%$ variance in population reproducibility. The USP considers the population test

valid if the variance is between -50% and $+300\%$ of the label claim. These data would indicate no significant difference in any of the population determinations.

4. The D-value of unexposed SGMStrips shipped to and from Europe, then tested 112 days after the initial D-value determination had a variance of -3% to -4% . SGM normally expects a variance of $\pm 10\%$ when performing replicate D-values. The USP considers a D-value test valid if it is within $\pm 20\%$ of the label claim. Therefore, no significant difference was observed due to shipping.
5. The D-values of exposed strips cultured within four (4) hours of exposure and units shipped to Europe and back varied from -3% to -15% . Strips exposed and held at SGM in controlled room temperature until the shipped units were returned and cultured varied from -4% to -14% . This is within the acceptable variance of $\pm 20\%$.
6. The time delay in culturing exposed strips was 71 days. This data is similar to the units cultured within four (4) hours of exposure.
 - 6.1. Fewer positive samples were observed in the 71 day delay than in the initial testing. However, in almost all tests the 100% survival time and 100% kill time were the same for both immediate and delayed culturing. It could be concluded that some injured spores did not survive the 71 day delay in culturing regardless of transit conditions, but this variance is within the limits of acceptable experimental error.
7. No significant change in population or D-value was found when comparing data of unexposed strips before shipping, after shipping, and stored at controlled room temperature.
8. There was no significant adverse effect on the SGMStrip biological indicators used in this study when exposed to temperatures between 42.02°C and 13.95°C , with humidity levels between 78.39% and 12.06% .
9. There was no significant adverse effect on SGMStrip performance compared to labeled claims with 71 days culture delay after exposure.

VI. Summary:

This study was undertaken to document the effects of transient environmental conditions that occur during the routine shipment of SGM's biological indicator products. The objective was to determine if these conditions have an effect on SGMStrip biological indicators containing *Bacillus stearothermophilus* spores. Three (3) lots of SGMStrips each manufactured from a different spore crop were shipped to Europe and back. Each lot was shipped separately on different days. Shipment 2 made two (2) complete cycles

to Europe and back to SGM. Each shipment contained standard product samples (unexposed), product samples exposed to fractional sterilization cycles and a Tinytag^{Plus} humidity and temperature recorder. Each shipment was returned to SGM for evaluation and analysis.

The environmental conditions during expedited UPS shipments averaged between 22.4°C and 23.4°C. The USP vol. 24 definition of controlled room temperature requires a mean kinetic temperature of 25°C or less. The conditions were within the controlled room temperature criteria for 99% of the time in transit. Short excursions occurred up to 42°C and as low as 13°C. Humidity conditions for long-term storage are recommended to be within 20% and 70% RH. The transient conditions ranged from 12% to 78% RH. The product was between the recommended value 99% of the time.

Transit time for the three shipments to return to SGM ranged from 33 to 43 days.

No significant differences were observed in populations or D_{121} -values of the unexposed biological indicators subjected to transient shipping conditions.

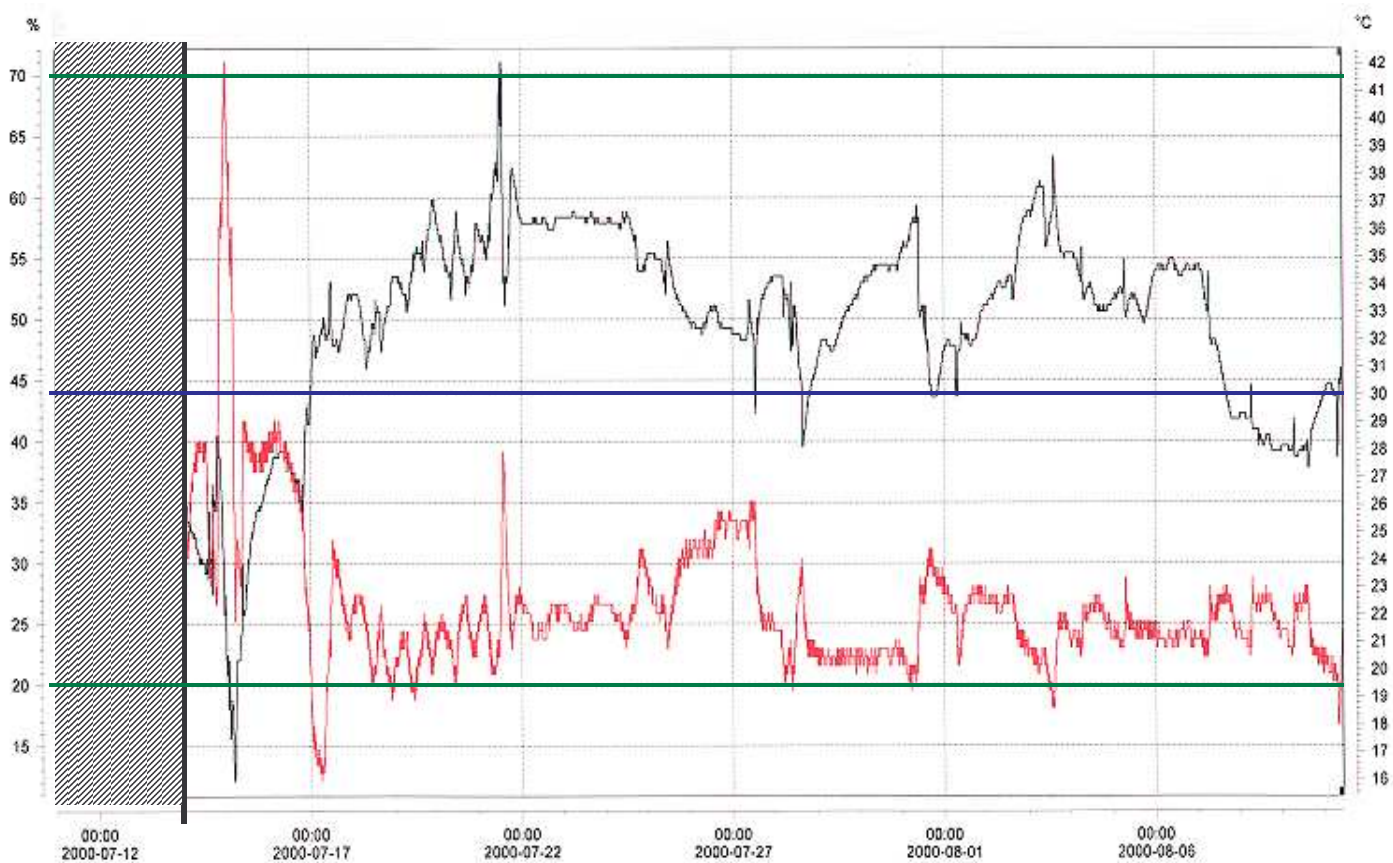
The SGMStrips that were exposed to fractional cycles also yielded an acceptable D_{121} -value even though culture time was delayed 71 days.

This study indicates that shipping conditions have no adverse effect on SGMStrips containing *B. stearothermophilus* spores.

Written by: _____ Date: May 14, 2001
Janice Fries
Microbiological Scientist

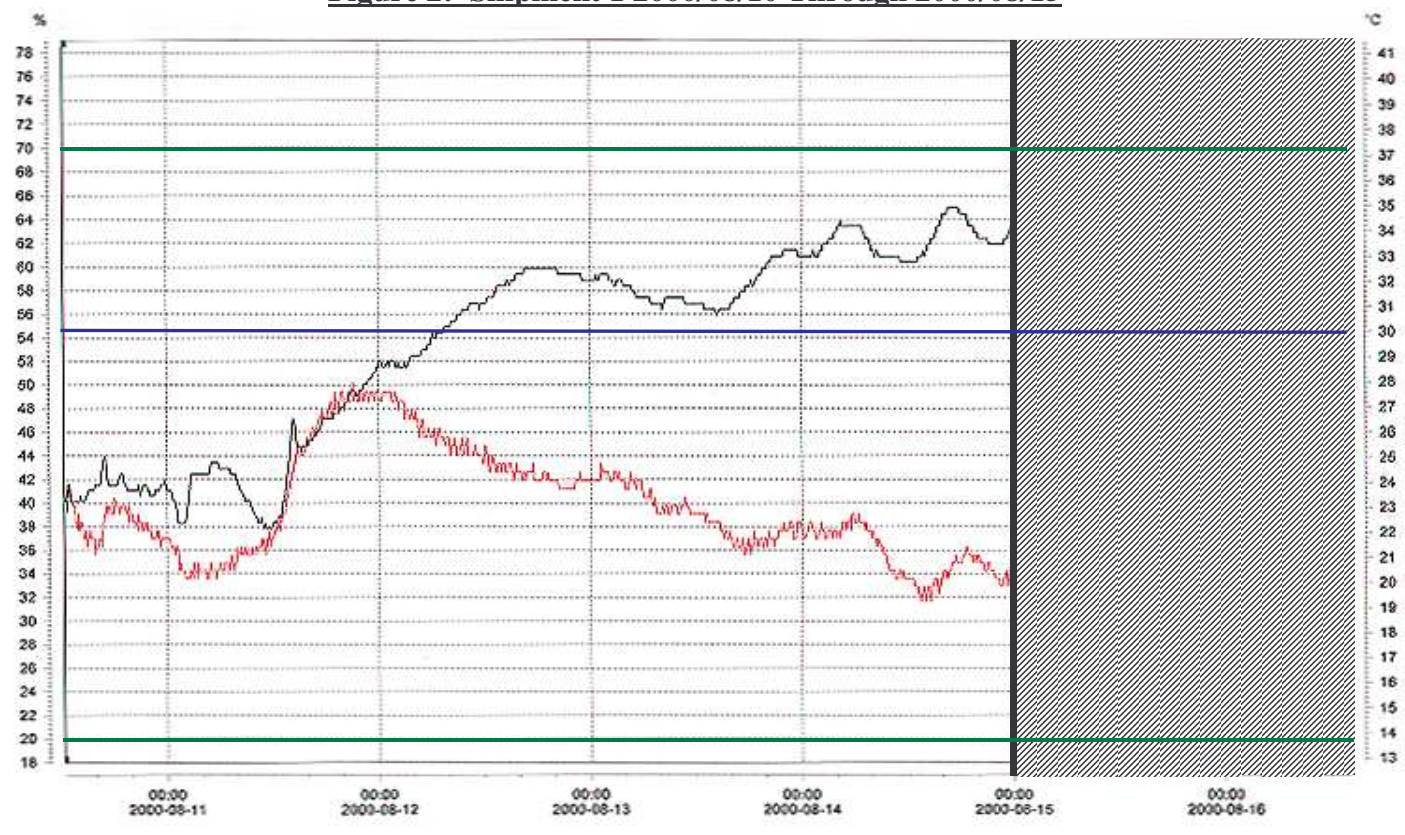
Approved by: _____ Date: May 14, 2001
Kurt McCauley, Microbiologist
Laboratory Manager

Figure 1: Shipment 1 2000/07/14 Through 2000/08/10



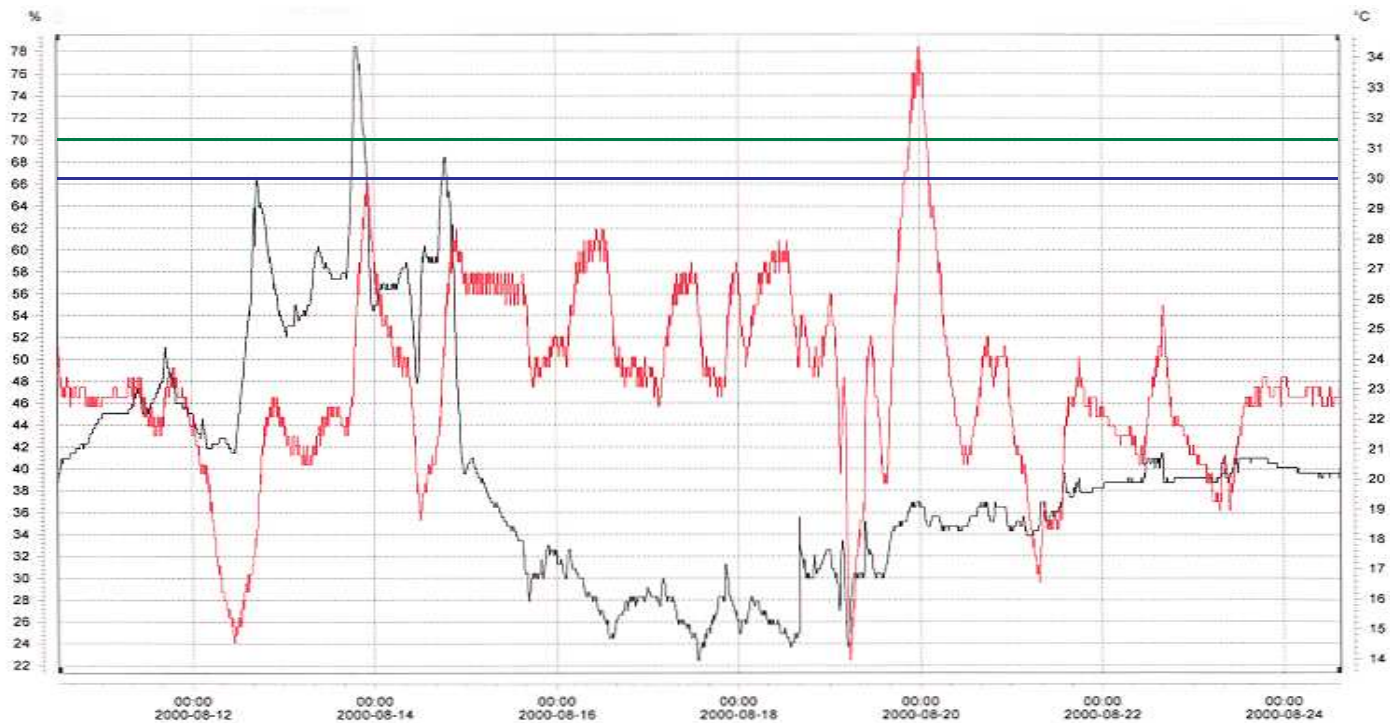
Temperature (°C) ————
 Humidity (%) ————
 Maximum Controlled Room Temperature Level (30°C) ————
 Label Humidity Range (20%-70%) ————

Figure 2: Shipment 1 2000/08/10 Through 2000/08/15



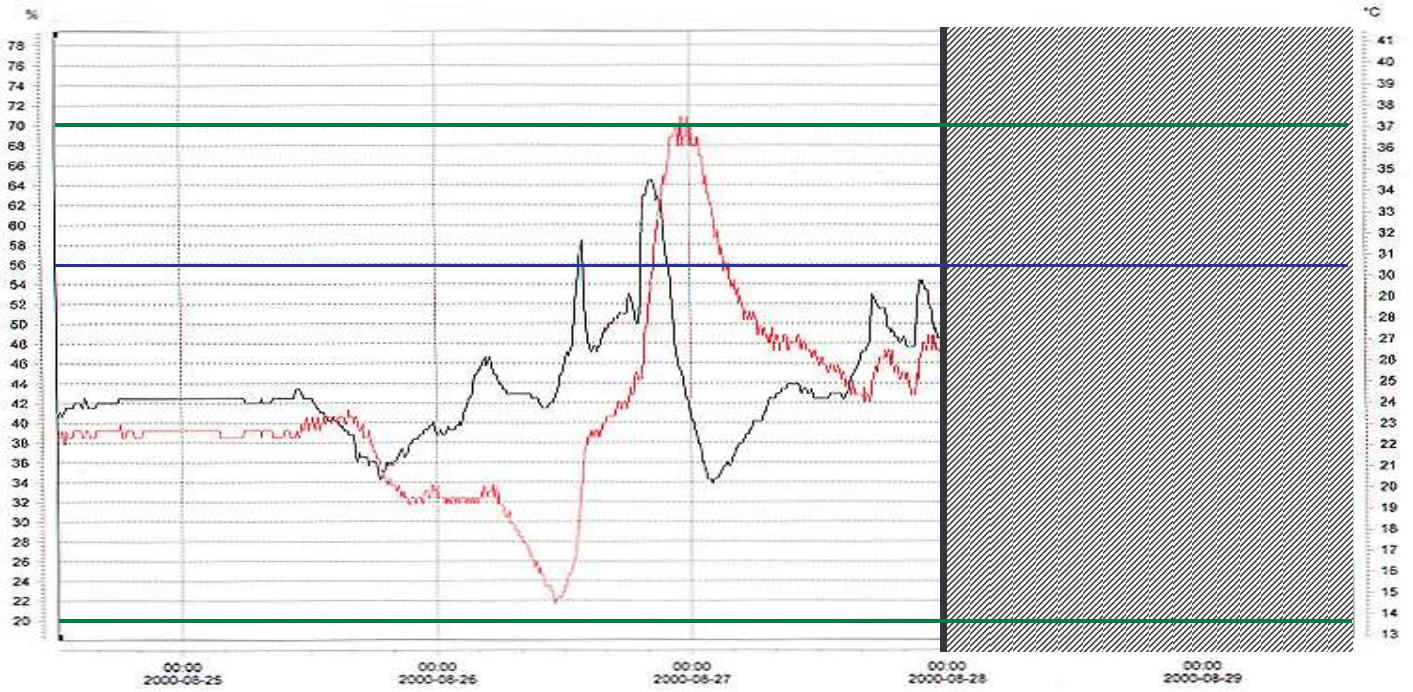
Temperature (°C) ————
Humidity (%) ————
Maximum Controlled Room Temperature Level (30°C) ————
Label Humidity Range (20%-70%) ————

Figure 3: Shipment 2 2000/08/10 Through 2000/08/24



Temperature (°C) ————
Humidity (%) ————
Maximum Controlled Room Temperature Level (30°C) ————
Label Humidity Range (20%-70%) ————

Figure 4: Shipment 2 2000/08/24 Through 2000/08/28



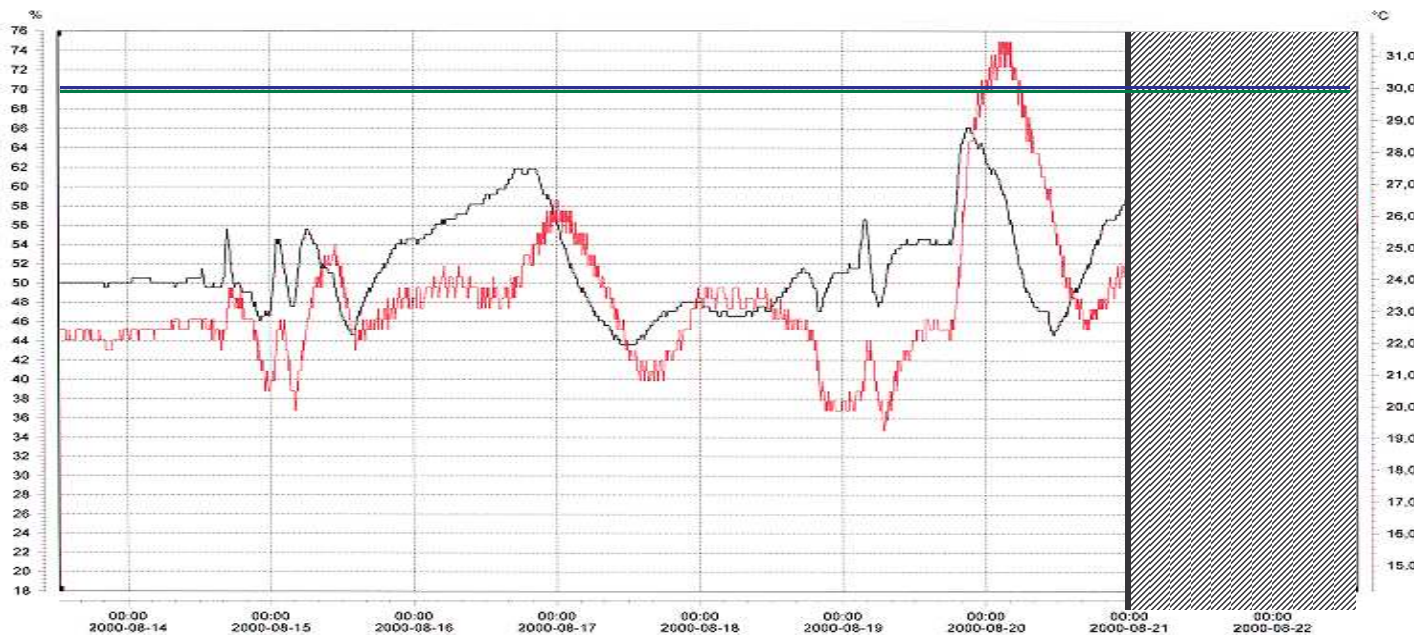
Temperature (°C) —
 Humidity (%) —
 Maximum Controlled Room Temperature Level (30°C) —
 Label Humidity Range (20%-70%) —

Figure 5: Shipment 3 2000/07/18 Through 2000/08/10



Temperature (°C) ————
 Humidity (%) ————
 Maximum Controlled Room Temperature Level (30°C) ————
 Label Humidity Range (20%-70%) ————

Figure 6: Shipment 3 2000/08/10 Through 2000/08/21



Temperature (°C) ————
 Humidity (%) ————
 Maximum Controlled Room Temperature Level (30°C) ————
 Label Humidity Range (20%-70%) ————