

REPORT ON

Destruction of Spores on Building Decontamination Residue in a Commercial Autoclave

National Homeland Security Research Center Office of Research and Development



Destruction of Spores on Building Decontamination Residue in a Commercial Autoclave

by:

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NOTICE

The U.S. Environmental Protection Agency (EPA), through its Office of Research and Development, funded this study under Contract Number EP-C-04-056, Work Assignment 0-7 to Eastern Research Group, Inc. (ERG). This report presents the methodology followed and the results of this study to evaluate the effectiveness of a commercial autoclave sterilizing simulated building decontamination residue. Simulated building decontamination residue consisting of wallboard, ceiling tiles, carpet, and upholstered furniture was prepared with 10⁶ population biological indicator test strips of *Geobacillus stearothermophilus*. The residue was then autoclaved under different conditions to evaluate the influence of the following variables on sterilization: time, temperature, pressure, item type, moisture content, packing density, packing orientation, autoclave bag integrity, and autoclave process sequence. While the results of this study provide valuable data on autoclave performance, this report is not EPA guidance and should not be viewed as such.

Mention of trade names, products, or services does not convey, and should not be interpreted as conveying, official EPA approval, endorsement, or recommendation.

This report has been subjected to the Agency's peer and administrative review and has been approved for publication as an EPA document.

FOREWARD

The U.S. EPA National Homeland Security Research Center (NHSRC),
Decontamination and Consequence Management Division (DCMD), one of three divisions of
NHSRC, is located in Research Triangle Park, North Carolina. The current focus of DCMD is on
the decontamination of buildings that have been intentionally contaminated with biological or
chemical agents. DCMD scientists study the biological or chemical contamination of air and
indoor surfaces; provide methods for upgrading buildings in ways that increase occupant
protection; supply information on decontamination methods, including safety, efficiency, cost;
and analyze disposal options for decontamination wastes.

This study was conducted as part of the DCMD research goal of evaluating commercial decontamination methods and systems. This report is being published to disseminate the findings of this study to the potential user community and other interested parties.

ACKNOWLEDGMENTS

This study was led by Dr. Paul Lemieux, U.S. EPA, Office of Research and Development, National Homeland Security Research Center, Decontamination and Consequence Management Division. ERG prepared simulated building decontamination residue and conducted the autoclave testing. The ERG test team included Roy Sieber, Aaron Osborne, Scott Sholar, and Steve Strackbein. Dave Dayton of ERG designed and built the temperature acquisition system described herein. Dr. Alan Woodard, New York State Department of Environmental Conservation, provided invaluable technical input during the planning and conduct of this study. The autoclave test would not have been possible without the facility access, cooperation, and technical expertise provided by Healthcare Environmental, Inc. Thank you to Richard Geisser, Vice President, Russ Hilton, Plant Manager, and all the dedicated members of the Healthcare Environmental team.

ABSTRACT

In the event of a terrorist attack on a building where biological weapons such as anthrax might be used, much of the porous material in the building will be shipped for disposal after decontamination activities. This material is collectively termed "building decontamination residue" (BDR). Although the BDR will have been disinfected or decontaminated, it is possible that residual biological agent will remain in the material.

Autoclaves are commonly used to sterilize regulated medical waste by exposing the waste to elevated pressures and temperatures for extended periods of time (e.g., 31.5 psig, 275°F, and 40 minutes). However, some types of BDR may be densely packed or have low thermal conductivity and may require longer periods of time to reach the operating temperature of an autoclave. This report addresses whether the standard operating procedure in a commercial autoclave will provide sufficient time/temperature/pressure to adequately destroy bacteria spores bound on BDR.

This study investigated the effect of several variables related to autoclaving BDR, including time, temperature, pressure, item type, moisture content, packing density, packing orientation, autoclave bag integrity, and autoclave process sequence. The test team created simulated BDR from wallboard, ceiling tiles, carpet, and upholstered furniture, embedded with 10^6 population *Geobacillus stearothermophilus* biological indicator (BI) strips and thermocouples to obtain time/temperature profile data associated with each BI strip.

Study results indicate that bags of BDR should be placed in an autoclave so that all sides of individual bags are exposed to autoclave conditions, and not nested or stacked in a manner that precludes full exposure. All materials tested were effectively sterilized when dry. Increasing moisture content made autoclaving more difficult, but wet wallboard and ceiling tiles were also effectively sterilized. Autoclave cycles of 120 minutes at 31.5 psig/ 275°F and 75 minutes at 45 psig/ 292°F effectively sterilized the BDR material. Two standard autoclave cycles of 40 minutes and 31.5 psig/ 275°F run in sequence proved to be particularly effective, probably because the second cycle's evacuation step pulled the condensed water out of the pores of the materials, allowing effective steam penetration.

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1.0 Introduction

In the event of a terrorist attack on a building where biological weapons (BW) such as anthrax might be used, much of the porous material in the building will be shipped for disposal after decontamination activities. These materials are collectively termed "building decontamination residue" (BDR). Although the BDR will have been disinfected or decontaminated, it is possible that residual BW agent will remain in the material. Many of these materials might be tightly packed and possibly wet. Autoclaves are commonly used to effectively treat regulated medical waste by exposing the waste to elevated pressures and temperatures for extended periods of time (e.g., 31.5 psig, 275°F, and 40 minutes at the test facility). However, BDR has low thermal conductivity and may require more time to reach the operating temperature of an autoclave.

It is unknown whether the standard operating procedure in a commercial autoclave will provide sufficient time/temperature/pressure to adequately destroy bacteria spores bound on BDR. The primary objective of this study was to determine what recommended operating conditions at a commercial medical waste autoclave are sufficient to destroy bacteria spores found on BDR. The secondary objective of this study was to investigate the time/temperature dependence of *Geobacillus stearothermophilus* spore destruction as a function of autoclove operating conditions and BDR composition. The commercial autoclave tested is operated by Healthcare Environmental, Inc., in Oneonta, NY. Viability of bacteria spores was tested using 10⁶ population biological indicator (BI) strips of viable spores of *Geobacillus stearothermophilus*, embedded in the materials processed by the autoclave. BDR materials tested included carpeting, wallboard, and ceiling tiles, both dry and wetted with water. Additionally, a sofa was processed to test the efficacy of autoclaving upholstered furniture.

This study was performed according to an approved *Quality Assurance Project Pla (QAPP)*, *Destruction of Spores on Building Decontamination Residue in a Commercial Autoclave* (1).

2.0 EXPERIMENTAL APPROACH

2.1 <u>Autoclave Description</u>

This test was conducted at the Healthcare Environmental, Inc. facility located in Oneonta, Oswego County, approximately 90 miles from Albany, New York. The facility operates a permitted, regulated medical waste autoclave process with approximately 84 tons/day (TPD) capacity. The facility has two large autoclaves 8 feet in diameter and 32 feet long, which accept large bins (80 inches by 54 inches by 69 inches) on rollers. Each autoclave can process 6 bins, with a total mass of approximately 3,000-4,000 pounds per cycle. Photographs 17 through 20 show the autoclave configuration. All photographs of the test are provided in Appendix A to this report.

The nominal autoclave operating cycle time is 40 minutes plus cool-down time to prepare for subsequent charges. At the start of each cycle, the autoclave is sealed and air is evacuated for 3 minutes using a vacuum pump to approximately -10 psig. Steam is then injected to reach and maintain the desired operating pressure and temperature, which are typically achieved in approximately 5 minutes. The nominal operating conditions during the cycles are 31.5 psig and 275°F. Steam is injected through three ports at the top of the autoclave, located at the front, center and rear. The steam is injected over distributor plates to cause turbulent, disbursed steam flow throughout the autoclave. At the end of each cycle, steam is evacuated by again pulling vacuum. Both autoclave units are identical. The facility continuously measures the operating temperature and pressure within each autoclave unit using a digital readout and paper chart recorder.

2.2 Testing Approach

Autoclave performance was judged based on two parameters: real-time measurements from thermocouples embedded in each simulated load of BDR material tested and viability of 10⁶ *Geobacillus stearothermophilus* BI test strips embedded within each load tested. The testing comprised a series of test runs at different conditions on one of the facility autoclaves (Unit A1). Section 2.3 discusses the conditions tested.

For each test run, the BDR material processed was wired with 24 thermocouples to record the time/temperature profile at different locations embedded within the load. A BI pouch was paired with a thermocouple at each test location. Each BI pouch contained two *Geobacillus stearothermophilus* indicator strips, labeled 'A' and 'B'. After the test, the A strips were analyzed for a growth/no-growth indication, and a population assay was performed on the B strips if the A strips grew, as discussed in Section 3.2. Additionally, control thermocouples not embedded in BDR recorded the temperature inside and outside the autoclave. Three types of control BI test pouches, further explained in Section 3.3.2.4, were also collected: BI test pouches fully exposed to the autoclave conditions, BI test pouches packaged and handled similarly to other BDR but not autoclaved, and duplicate BI test pouches.

2.3 <u>Test Matrix and Conditions</u>

As discussed in the QAPP, the following variables were identified as having a potential impact on sterilization capability:

- 1. Item type;
- 2. Autoclave packing density (i.e., loose packing versus dense packing);
- 3. Moisture content of autoclaved materials:
- 4. Autoclave temperature/pressure; and
- 5. Time in autoclave.

The test matrix presented in Table 2-1 was designed to investigate the effects of each of these variables.

Temperature data from initial test runs indicated that internal temperatures of densely packed material responded slowly to autoclave conditions, and therefore, this material was not likely being sterilized after 120 minutes, the maximum autoclave run time established for the test. After discussion among the EPA Work Assignment Manager (WAM), ERG WAM, New York State Department of Environmental Conservation (NYSDEC) representative, and the autoclave facility manager, originally planned Runs 2, 5, 6, and 7 were deleted and three

additional factors were identified and tested to determine if they improved sterilization capability:

- 1. Positioning sample bags of BDR vertically instead of horizontally;
- 2. Cutting open the bags of BDR to facilitate steam penetration; and
- 3. Running two shorter process cycles in sequence instead of one long cycle.

A revised test matrix was developed based on the temperature results of the initial runs and the objective of testing additional factors to improve sterilization. The changes to the test matrix were based partially on altering test conditions within easily adjusted facility operating constraints. Table 2-2 presents the revised test matrix. All run numbers discussed in this document are the revised test matrix run numbers. Run numbers were assigned based on the set of prenumbered thermocouples and corresponding BDR used in the run. Runs are typically discussed in the order in which they were conducted: 1, 2, 4, 8, 5, 6. Each variable tested is discussed in further detail below.

2.3.1 Item Type

The BDR tested included ½-inch thick, 4 feet by 8 feet sheets of LaFarge regular grade drywall (wallboard), 5%-inch thick, 2 feet by 4 feet Armstrong Contractor Series Ceiling Panels Model #942 (ceiling tiles), and Mannington Nepenthe II Blue commercial grade carpeting (Nylon 6,6 fibers). New, unused wallboard and ceiling tiles were purchased from a building material supplier. Used commercial carpeting, in rolls of varying sizes, was obtained from a carpet installation contractor. Additionally, a used queen-sized sleeper sofa was obtained from a thrift store.

Test material was cut up and packaged to simulate likely BDR generated from a building decontamination scenario. Decontamination personnel are expected to size BDR to be easily handled and pack it for shipment using a double-bagging technique. The techniques used are similar to those from the State Department Sterling, Virginia mail facility anthrax cleanup (2). The steps used to reduce the size and package each of these items are discussed below.

Table 2-1. Originally Planned Healthcare Environmental Autoclave Test Matrix

Run	Item Type	Temp/ pressure	Time	Position/Bin 1	Position/Bin 2	Position/Bin 3	Position/Bin 4	Position/Bin 5	Comments
1	Mixed, loose pack	275°F/ 31.5 psig	Target time at 250°F (121°C) for all thermocouples is 15 minutes.	Thermal Mass (~700lbs)	Loose Pack CT, Dry WB, Dry ~250 lbs (10 TC)	Loose Pack CT, Wet WB, Wet ~300 lbs (10 TC)	Thermal Mass (~700 lbs)	Carpet, small rolls, dry (4 TC)	Loose packing will provide one level of bagged BDR in each bin. (6 x 40 lb. bags) Steam can easily penetrate to top and bottom of all bags.
2	·	275°F/ 31.5 psig	Provide a minimum run time of 40 minutes. Extend run time as needed to	Thermal Mass (~700lbs)	Dense Pack WB, Dry ~700 lbs (12 TC)	Dense Pack WB, Wet ~850 lbs (12 TC)	Thermal Mass (~700 lbs)	Open	Similar to Run 1, but packing is denser, approximately 3 to 4 levels deep (25 x 40 lb. bags per bin)
3	Wallboard, dense pack	292°F/ 45 psig	achieve temperature targets.	Thermal Mass (~700lbs)	Dense Pack WB, Dry ~700 lbs (12 TC)	Dense Pack WB, Wet ~850 lbs (12 TC)	Thermal Mass (~700 lbs)	Open	Similar to Run 2, but temperature is increased to upper limit.
4	Carpet	Select based on runs 1, 2, 3		Thermal Mass (~700lbs)	Small rolls, loose pack, wet and dry ~250 lbs (8 TC)	Small rolls, dense pack wet and dry ~700 lbs (8 TC)	Large roll, wet (8 7	rc)	Test packing style and temperature profile within carpet roll. Array thermocouples at varying depths within rolls.
5	Ceiling tiles, dense pack	275°F/ 31.5 psig		Thermal Mass (~700lbs)	Dense Pack CT, Dry ~700 lbs (12 TC)	Dense Pack CT, Wet ~850 lbs (12 TC)	Thermal Mass (~700 lbs)	Open	Similar to Run 2, ceiling tile instead of wallboard
6	Ceiling tiles, dense pack	292°F/ 45 psig		Thermal Mass (~700lbs)	Dense Pack CT, Dry ~700 lbs (12 TC)	Dense Pack CT, Wet ~850 lbs (12 TC)	Thermal Mass (~700 lbs)	Open	Similar to Run 5, temperature increased to upper limit.
7	Carpet	Select based on prior runs		Thermal Mass (~700lbs)	Small rolls, loose pack, wet and dry ~250 lbs (8 TC)	Small rolls, dense pack wet and dry ~700 lbs (8 TC)	Large roll, wet (8 7	TC)	Test packing style and temperature profile within carpet roll. Array thermocouples at varying depths within rolls.
8	Mixed, loose pack	292°F/ 45 psig		Thermal Mass (~700lbs)	Loose Pack CT, Dry WB, Dry ~250 lbs (10 TC)	Loose Pack CT, Wet WB, Wet ~300 lbs (10TC)	Sofa (4 TC)		Similar to run 1, temperature at upper limit.

(x TC) designates "x" thermocouples per bin.
WB = Wallboard.
CT = Ceiling Tile.

CP = Carpet.

 Table 2-2. Healthcare Environmental Autoclave Test Matrix as Completed

Run	Original Matrix Run	Item Type	Temp/ pressure	Time	Position/Bin 1	Position/Bin 2	Position/Bin 3	Position/Bin 4	Position/Bin 5	Comments		
1	1	Mixed, loose pack	275°F / 31.5 psig	120 min	Thermal Mass (~800lbs)	Loose Pack WB, Wet and Dry ~215 lbs (10 TC)	Loose Pack CT, Wet and Dry ~170 lbs (10 TC)	rolls, dry (~800 lbs) ~150 lbs (4 TC)		rolls, dry (~800 lbs)		One level of bagged BDR in each bin. (6 bags) Steam could easily penetrate to top and bottom of all bags; however, still took a considerable amount of time.
2	3	Wallboard, dense pack	292°F / 45 psig	120 min		Dense Pack WB, Wet ~850 lbs (12 TC)	Dense Pack WB, Dry ~750 lbs (12 TC)	Thermal Mass (~800 lbs) Open		Went directly to higher temperature (skipped originally planned Run 2) because of the slow heating of Run 1.		
4	4		275°F / 31.5 psig	120 min		Small rolls, dense pack, wet and dry ~250 lbs (8 TC)	Small rolls, loose pack wet and dry ~850 lbs (8 TC)	Large roll, wet (8 TC)				Test packing style and temperature profile within carpet roll. Array thermocouples at varying depths within rolls.
8	8	Mixed, loose pack	292°F / 45 psig	75 min	Thermal Mass (~800lbs)	Loose Pack WB, Wet and Dry ~215 lbs (10 TC)	Loose Pack CT, Wet and Dry ~170 lbs (10 TC)	Sofa (4 TC)		Similar to run 1, temperature at upper limit. Run time was terminated after 75 minutes due to concern of the sofa temperature rising significantly above the autoclave temperature, indicating the potential initiation of exothermic reaction.		
5	Not Included	Mixed, loose vertical pack		2 cycles each 40 min		Vertical Pack CT, Wet and Dry CP, Wet and Dry ~125 lbs (12 TC)	Vertical Pack CT, Wet and Dry WB, Wet and Dry ~125 lbs (12 TC)	Thermal Mass (~800 lbs) Open		Test to determine if vertical packing and two sequential shorter cycles would be effective.		
6	Not Included	Mixed, loose vertical pack		2 cycles each 40 min	'	Vertical Pack CT, Wet and Dry CP, Wet and Dry ~125 lbs (12 TC)	Vertical Pack CT, Wet and Dry WB, Wet and Dry ~125 lbs (12 TC)	Thermal Mass (~800 lbs)	Open	Similar to Run 5, but all bags were cut.		

(x TC) designates "x" thermocouples per bin.
WB = Wallboard.
CT = Ceiling Tile.
CP = Carpet.

2.3.1.1 Wallboard

The wallboard was cut into approximately 2 feet by 2 feet sections as described in the QAPP. Sample BDR bags were formed by placing five, 2 feet by 2 feet sections face to face in autoclave bags. Samples requiring wetting were submerged in tank of water for 30 seconds and placed on a drain rack for 5 minutes prior to being placed in the bag. Dry test bags weighed approximately 34 pounds, and wet bags weighed approximately 37 pounds. Samples were double bagged in 1.8 mil polypropylene autoclave bags, and the bags were individually goosenecked and taped shut using duct tape. A section of nylon rope was attached to the gooseneck to allow ERG personnel to easily and safely load and unload the bags from the autoclave bins.

Three types of wallboard bags were created. Some test bags were assembled with one thermocouple and one test strip pouch placed together, between the second and third wallboard section. These are referred to as "1-sample" bags. Other test bags were assembled with three thermocouples paired with three test strip pouches placed between the first and second, second and third, and fourth and fifth wallboard sections. These are referred to as "3-sample" bags. Photographs 2 through 8 in Appendix A show how the bags were assembled. Additional bags were made without thermocouples and BI test pouches to be used as fillers when packing the autoclave bins.

Bags were placed in the autoclave bins in either a loose packing or dense packing arrangement as indicated on the test matrix in Table 2.2. In the loose packing arrangement, six bags were placed per bin: two 3-sample bags and four 1-sample bags. Ten total samples were collected per bin in loose density packing. See Photograph 27 for the loose packing arrangement of wallboard bags.

In the dense-packing arrangement, 23 bags were placed in each bin including three, 3-sample bags and three 1-sample bags. The remaining 17 bags were used to fill out the load. Bags were layered within the bin, in approximately three to four layers of four to six bags each. Bags were placed in the bin with one 3-sample and one 1-sample bag in each layer, so that sample bags were dispersed throughout the loaded bin. Twelve total samples were collected per

bin in the dense packing arrangement. See the side view sketch in Figure 2-1 and Photograph 29 dense packing arrangement of bags.

For the vertical packing arrangement, one dry 3-sample and one wet 3-sample bag were placed in a bin. Ropes tied to opposite edges of the autoclave bin wall were used to maintain the vertical alignment, as shown in Photograph 35.

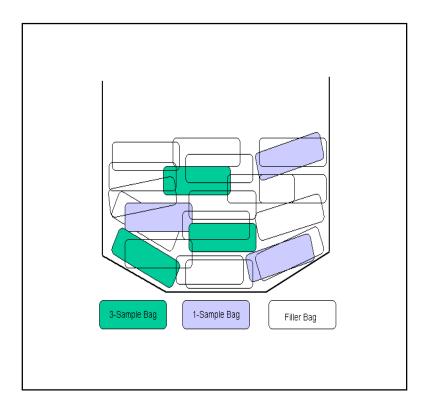


Figure 2-1. Side View Sketch of Dense Packing Arrangement

2.3.1.2 Ceiling Tiles

Ceiling tiles were cut into approximately 2 feet by 2 feet sections as described in the QAPP. Samples were prepared similarly to wallboard; however, bags contained nine 2 feet by 2 feet sections placed face to face. Dry test bags weighed approximately 23 pounds, and wet bags weighed approximately 31 pounds.

One-sample bags contained one thermocouple and one test strip pouch placed together, between the fourth and fifth ceiling tile section. Three-sample bags contained three thermocouples paired with three test strip pouches placed between the second and third, fourth and fifth, and seventh and eighth ceiling tile sections. Additional bags were made without thermocouples and BI test pouches to be used as fillers.

As discussed previously, originally planned runs of densely packed ceiling tiles were deleted from the test matrix. In the loose packing arrangement, two 3-sample bags and four 1-sample bags were placed per bin. Ten total samples were collected per bin in loose density packing. See the Photograph 30 for the loose packing arrangement of bags.

For the vertical packing arrangement, one dry 3-sample and one wet 3-sample bag were placed in a bin. Ropes tied to opposite edges of the autoclave bin wall were used to maintain the vertical alignment, as shown in Photograph 35.

2.3.1.3 Carpet

Carpet was tested in two general configurations, small and large rolls. For small rolls, the contractor cut the carpet into strips 26 inches wide by 20 feet long, representing how carpet would most likely be removed from a building. Samples requiring wetting were soaked with a hose-end sprayer. After wetting, samples were rolled and placed on end to allow free-flowing water to drain. Small rolls were bagged in a similar manner to wallboard and ceiling tiles. Dry test bags weighed approximately 26 pounds, and wet bags weighed approximately 40 pounds. As a worst case, larger sections of carpet 6 feet wide and 24 feet long also were requested and obtained from the contractor. Large rolls were only prepared wet, and weighed approximately 200 pounds, which represented the maximum size that could be handled by two workers. Large rolls were wrapped in polypropylene and all seams sealed with duct tape. Photographs 10 through 15 in Appendix A show the assembly process for carpet bags.

For the small carpet rolls, 1- and 3-sample bags were prepared. One-sample bags contained one thermocouple and one test strip pouch placed together, at the approximate midpoint of the radius of the carpet roll. Three-sample bags contained three thermocouples paired

with three test strip pouches placed two laps in from the top, at the mid-point of the radius, and two laps from the center of the carpet roll. Additional bags were made without thermocouples and BI test pouches to be used as fillers.

Bags with small rolls of carpet were placed in the autoclave bins in either a loose packing or dense packing arrangement. In the loose packing arrangement, two, 3-sample bags and two, 1-sample bags were placed in a bin. Bags that did not contain sample points were used to fill out the load. Eight total samples were collected per bin in the loose packing arrangement.

In the dense packing arrangement, shown in Photograph 33, 25 bags were placed per bin including two 3-sample bags and two 1-sample bags. The remaining 21 bags were used to fill out the load. Bags were layered within the bin, in approximately three to four layers of six to eight bags each. Bags were placed in the bin so that two 3-sample bags were placed in the middle layer and two 1-sample bags were placed in the bottom layer. Eight total samples were collected per bin in the dense packing arrangement.

For the vertical packing arrangement, one dry 3-sample and one wet 3-sample bag were placed in a bin. Ropes tied to opposite edges of the autoclave bin wall were used to maintain the vertical alignment, as shown in Photograph 35.

The large roll of carpet was assembled with eight thermocouples paired with eight test strip pouches placed at eight locations throughout the roll. The locations were arrayed progressively deeper within the rolled carpet, as depicted in Figure 2-2. The large roll of carpet was placed in the autoclave on a wood pallet rather than in a bin, as shown in Photograph 34.

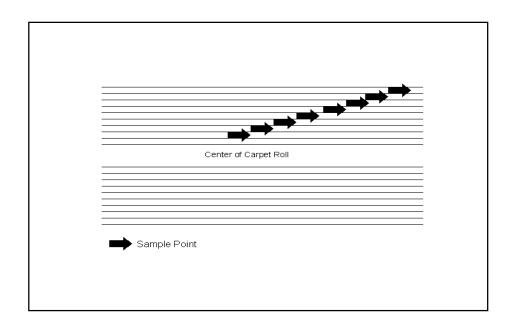


Figure 2-2. Configuration of Sample Points in a Large Carpet Roll

2.3.1.4 Sofa

A used queen-sized sleeper sofa was obtained from a thrift store and autoclaved in Run 4. The sofa was not wetted prior to being autoclaved. Four thermocouple and test strip pouches were paired and embedded in different locations in the sofa. Samples were inserted in holes cut approximately 6 inches deep in a back cushion and a seat cushion. The holes were then covered with duct tape. One sample was also placed in between the folded sleeper mattress, and one in between the seat cushions. The sofa was wrapped in polypropylene and all seams sealed with duct tape, as shown in Photograph 16. The sofa was placed in the autoclave on a sheet of plywood.

2.3.2 Autoclave Packing Density

The Healthcare Environmental autoclave is designed to operate with six loaded bins of material, loaded with approximately 700 pounds of material each.

Wallboard was tested at two different bin packing densities. Low density packing involved placing six bags in a bin. In a low density arrangement, shown in Photograph 27, the

bags formed a single layer at the base of the bin, and all bag surfaces were readily exposed to autoclave temperatures. High density packing, shown in Photograph 29, involved placing 23 bags in each bin. The bags were layered approximately three to four levels deep, exposing some bags directly to autoclave conditions while others were buried within the load in the bin. Ceiling tiles were only tested in a low density arrangement, as described above for wallboard. Runs of densely packed ceiling tiles were deleted from the test matrix because densely packed BDR material could not be brought up to autoclave temperatures within the 120-minute duration specified in the test plan.

Carpet was tested in three configurations. Small rolls, approximately 1 foot in diameter and 26 inches long, were placed in bags. Six bags were placed in a bin for low density packing, as above (see Photograph 31). Twenty-five bags were placed in a bin for high density packing, as above (see Photograph 33). In addition, the effect of the autoclave on a large, intact roll of carpet 6 feet long and approximately 1.5 feet in diameter, shown in Photograph 34, was tested in Run 4.

2.3.3 Moisture Content

Materials were tested both dry and wet. In this context, dry means in as-is condition at ambient humidity, with no additional moisture added. Wet conditions were created by briefly immersing wallboard and ceiling tile pieces in water and allowing them to drain. Immediately after draining, the wallboard and ceiling tiles were placed in sealed polyethylene bags. Carpet was soaked with a hose-end sprayer until saturated, and then allowed to drain. After draining, carpet pieces were rolled up and sealed in either polyethylene bags (small rolls) or wrapped in polyethylene sheeting (large rolls). Wet and dry bags of BDR were weighed to determine the additional water weight. On average, wetting increased the weight of wallboard bags by 9 percent, ceiling tile bags by 34 percent, and carpet bags by 53 percent.

2.3.4 Temperature and Pressure

Temperature and pressure are related variables, as the autoclave is designed to operate at saturated steam conditions. The study investigated two conditions: 31.5 psig / 275°F,

the typical operating pressure of the autoclave, and 45 psig / 292°F, the maximum operating pressure of the autoclave. Pressure is the parameter controlled by the autoclave controller. These temperatures and pressures are as measured in the interior space of the autoclave. Temperatures within the autoclaved items lagged behind these temperatures, as discussed in Section 2.3.5.

2.3.5 Time

A minimum run time of 40 minutes at elevated temperature was established, according to standard operation of the Healthcare Environmental autoclave. Literature data indicate that 15 minutes at 250°F is required for assured moist heat sterilization (3,4). Therefore, the test plan called for extending the run time beyond 40 minutes to achieve a 250°F temperature target at all, or at least most embedded thermocouples. Even if the 250°F target had not been achieved, the test plan established a maximum run time of 120 minutes to enable the autoclave to process multiple test runs each day. Runs 1, 2, and 4 were terminated after 120 minutes, prior to all thermocouples reaching the target temperature. Run 8 was stopped after 75 minutes due to concerns that the sofa temperature was rising above the temperature of the autoclave, indicating a potential exothermic reaction in the sofa. Because such a reaction and possible associated hazards were not well understood, the run was terminated. Conducting two 40-minute runs in sequence was investigated in Runs 5 and 6. This variation is discussed further in Section 2.3.8.

2.3.6 Packing Orientation

Material was tested both lying horizontally in the autoclave bins and positioned vertically, with all sides exposed. Material was positioned vertically by tying two ropes to the top of the bag and attaching the ends of the rope to opposite sides of the autoclave bin wall, as shown in Photograph 35. This packing orientation was introduced as a test variable to simulate using a rack system to position bags so that all sides are exposed to autoclave steam. We theorized that vertical orientation of the BDR would reduce compression from its own weight, and also would allow steam condensate to drain more easily as it formed. If these theories are correct, both would facilitate steam penetration and improve heating of the material in the autoclave.

2.3.7 Open Bags

All BDR was double-bagged in 1.8 mil polypropylene bags. The bags were individually goose-necked and sealed with duct tape. This procedure was adopted based on packaging information from the State Department Sterling, Virginia mail facility anthrax cleanup (2). After autoclaving, some of the bags had clearly ruptured due to temperature and pressure changes. However, in many cases bag surfaces bubbled and became deformed in the autoclave, but it was not clear if they had fully opened. To test if the bags opening had an effect on sterilization, two bags in Run 5 and all of the bags in Run 6 were opened prior to autoclaving, by slicing two sides of each bag open with a utility knife across their entire length.

2.3.8 Multiple Short Cycles

As steam in the autoclave was evacuated to end Runs 2, 4, and 8, the test team observed that, as the vacuum was drawn, most thermocouple readings converged toward a midpoint temperature. Not only were high readings falling, but most of the lower readings were rising and converged together. It is not known if this was a result of increased turbulence during the post-vacuum cycle, condensed water being drawn out of BDR under vacuum, or some combination of these and other factors. However, in consultation with EPA WAM, we decided that it would be worthwhile to further investigate this phenomenon. Therefore, in Runs 5 and 6, two complete normal autoclave operating cycles were run in succession. Each cycle consisted of a pre-vacuum, steam pressurization, and post-vacuum phase. The cycles were conducted in immediate succession and the autoclave remained sealed throughout both cycles.

2.4 Test Schedule

ERG conducted BDR size reduction, wetting, sample placement, and packaging at its Chantilly, Virginia facility between February 15 and February 24, 2005. Materials were stored at room temperature until March 1, 2005.

Materials were placed on truck trailers on March 1, 2005 and transported to Oneonta, New York by Roadway Express, Inc. Trailers were delivered in Oneonta on March 3, 2004. ERG sealed the trailers in Chantilly, and broke the seals in Oneonta.

Test materials were unloaded and staged for processing on March 4, 2005, and autoclaved on March 5 and 6, 2005.

3.0 RESULTS

This section presents the time/temperature, biological indicator, and quality assurance data collected during this test. Section 4 presents the analysis of the data.

3.1 <u>Time/Temperature Data</u>

Real-time temperature measurements were monitored and recorded at each sampling point using a GEC Instruments Model S27TC temperature measurement system and Type "T" thermocouples. Figures 3-1 through 3-6 (located at the end of this section) present plots of the time/temperature data recorded during each of the six runs. Temperature data were recorded at each location approximately every 10 seconds. The figures also include readings from the control thermocouple inside the autoclave, the reference thermocouple outside the autoclave, and the autoclave set point pressure/temperature. Note that Figures 3-1 through 3-6 are designed to present an overview of all time/temperature data associated with each run. Section 4.0 provides further analysis of these data and distinction between the variables.

The facility monitoring system collected additional process measurement data. Operating temperature and pressure within the autoclave were measured using the existing autoclave thermocouple and pressure gauge and synchronized against 24-hour clock time. The time, temperature, and pressure were recorded during the test on a 24-hour circular chart recorder.

3.2 Biological Indicator Data

A BI test pouch, containing two BI test strips, was placed at each sampling point. Each BI strip contained a 10⁶ population of *Geobacillus stearothermophilus* on Schleicher & Schuell filter paper (#470) encased in a glassine peel-open envelope. The test pouch consisted of medical grade paper with a plastic facing. Raven Biological Laboratories, Inc. (Raven) provided the BI pouches (American Type Culture Collection #7953, Lot #3167091, expiration January 2007). The strips within each pouch were designated 'A' strips and 'B' strips. Following the test, Raven cultured all A strips for an indication of growth or no-growth. For A strips indicating

growth, Raven performed a population assay of the B strip to quantify the survivor population. Table 3-1 presents the results from these analyses.

3.3 Quality Assurance Data

This section presents quality assurance data collected and compares all data collected with the acceptance criteria presented in Section 7.0 of the QAPP.

3.3.1 Process Measurements

Autoclave temperature, autoclave pressure, and run time were recorded on a 24-hour circular chart recorder. Record data where accurate to the following levels, meeting the acceptance criteria:

Autoclave temperature: ± 5°F
 Autoclave pressure: ± 0.5 psig
 Run time: ± 1 minute

3.3.2 Experimental Measurements

Quality data for each of the experimental measurements are presented in the following subsections.

3.3.2.1 Run Time

The temperature logging system was synchronized to \pm 1 minute with the autoclave data recorder clock at the beginning of each day. All time/temperature data was time stamped to \pm 1 second. All data was time stamped and therefore is considered usable.

Table 3-1. Biological Indicator Data

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Drv)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
1	101	WB	D	В	Loose Pack - Horizontal	79		No Growth	N/A
1	101	WB	D	В	Loose Pack - Horizontal	80	Duplicate	No Growth	N/A
1	102	WB	D	В	Loose Pack - Horizontal	81		No Growth	N/A
1	103	WB	D	В	Loose Pack - Horizontal	82		No Growth	N/A
1	104	WB	D	В	Loose Pack - Horizontal	83		No Growth	N/A
1	105	WB	D	В	Loose Pack - Horizontal	84		No Growth	N/A
1	106	CT	D	В	Loose Pack - Horizontal	85		No Growth	N/A
1	107	CT	D	В	Loose Pack - Horizontal	86		No Growth	N/A
1	108	CT	D	В	Loose Pack - Horizontal	87		No Growth	N/A
1	109	CT	D	В	Loose Pack - Horizontal	88		No Growth	N/A
1	110	CT	D	В	Loose Pack - Horizontal	89		No Growth	N/A
1	111	WB	W	В	Loose Pack - Horizontal	90		No Growth	N/A
1	112	WB	W	В	Loose Pack - Horizontal	91		No Growth	N/A
1	113	WB	W	В	Loose Pack - Horizontal	92		No Growth	N/A
1	114	WB	W	В	Loose Pack - Horizontal	93		No Growth	N/A
1	115	WB	W	В	Loose Pack - Horizontal	94		No Growth	N/A
1	115	WB	W	В	Loose Pack - Horizontal	95	Duplicate	No Growth	N/A
1	116	CT	W	В	Loose Pack - Horizontal	96		No Growth	N/A
1	117	CT	W	В	Loose Pack - Horizontal	97		No Growth	N/A
1	118	CT	W	В	Loose Pack - Horizontal	98		No Growth	N/A
1	119	CT	W	В	Loose Pack - Horizontal	99		No Growth	N/A
1	120	CT	W	В	Loose Pack - Horizontal	100		No Growth	N/A
1	121	СР	D	В	Loose Pack - Horizontal	165		No Growth	N/A
1	122	СР	D	В	Loose Pack - Horizontal	166		No Growth	N/A
1	123	СР	D	В	Loose Pack - Horizontal	167		No Growth	N/A
1	124	СР	D	В	Loose Pack - Horizontal	168		No Growth	N/A
1	125	N/A	N/A	N/A	Control Inside Autoclave	217	Run 1 Full Exposure Control	No Growth	N/A

Table 3-1 (Continued)

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Drv)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
2	201	WB	D	В	Dense Pack	1		No Growth	N/A
2	202	WB	D	T	Dense Pack	2		No Growth	N/A
2	203	WB	D	M	Dense Pack	3		No Growth	N/A
2	204	WB	D	M	Dense Pack	4		No Growth	N/A
2	204	WB	D	M	Dense Pack	13	Duplicate	No Growth	N/A
2	205	WB	D	M	Dense Pack	5		Growth	183,000
2	206	WB	D	M	Dense Pack	6		Growth	220,000
2	207	WB	D	T	Dense Pack	7		Growth	150,000
2	208	WB	D	T	Dense Pack	8		Growth	61,000
2	209	WB	D	T	Dense Pack	9		No Growth	N/A
2	210	WB	D	В	Dense Pack	10		No Growth	N/A
2	211	WB	D	В	Dense Pack	11		No Growth	N/A
2	212	WB	D	В	Dense Pack	12		No Growth	N/A
2	213	WB	W	T	Dense Pack	66		No Growth	N/A
2	214	WB	W	M	Dense Pack	67		No Growth	N/A
2	215	WB	W	В	Dense Pack	68		No Growth	N/A
2	216	WB	W	В	Dense Pack	69		No Growth	N/A
2	217	WB	W	В	Dense Pack	72	Duplicate	Growth	<100
2	217	WB	W	В	Dense Pack	70		No Growth	N/A
2	218	WB	W	В	Dense Pack	71		No Growth	N/A
2	219	WB	W	T	Dense Pack	73		Growth	283,000
2	220	WB	W	T	Dense Pack	74		Growth	9,330
2	221	WB	W	T	Dense Pack	75		Growth	13,000
2	222	WB	W	M	Dense Pack	76		Growth	47,300
2	223	WB	W	M	Dense Pack	77		Growth	13,000
2	224	WB	W	M	Dense Pack	78		Growth	39,700
2	225	N/A	N/A	N/A	Control Inside Autoclave	218	Run 2 Full Exposure Control	Growth	330

Table 3-1 (Continued)

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Drv)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
4	401	СР	W	N/A	N/A	136		Growth	63,700
4	402	СР	W	N/A	N/A	137		Growth	370,000
4	403	СР	W	N/A	N/A	138		Growth	473,000
4	404	СР	W	N/A	N/A	139		Growth	131,000
4	405	СР	W	N/A	N/A	140		Growth	140,000
4	406	СР	W	N/A	N/A	141		Growth	277,000
4	407	СР	W	N/A	N/A	142		Growth	280,000
4	408	СР	W	N/A	N/A	143		Growth	113,000
4	409	СР	D	В	Loose Pack - Horizontal	169		No Growth	N/A
4	410	СР	D	В	Loose Pack - Horizontal	170		Growth	72,000
4	411	СР	D	В	Loose Pack - Horizontal	171		Growth	54,300
4	411	СР	D	В	Loose Pack - Horizontal	172	Duplicate	Growth	13,700
4	412	СР	D	В	Loose Pack - Horizontal	173		Growth	100
4	413	СР	D	M	Dense Pack	174		Growth	117,000
4	414	СР	D	В	Dense Pack	175		Growth	537,000
4	415	СР	D	В	Dense Pack	176		Growth	197,000
4	416	СР	D	В	Dense Pack	177		Growth	347,000
4	417	СР	W	В	Loose Pack - Horizontal	187		Growth	<100
4	418	СР	W	В	Loose Pack - Horizontal	188		No Growth	N/A
4	419	СР	W	В	Loose Pack - Horizontal	189		No Growth	N/A
4	420	СР	W	В	Loose Pack - Horizontal	190		No Growth	N/A
4	420	СР	W	В	Loose Pack - Horizontal	191	Duplicate	No Growth	N/A
4	421	СР	W	M	Dense Pack	192		Growth	100,000
4	422	СР	W	Т	Dense Pack	193		Growth	18,300
4	423	СР	W	Т	Dense Pack	194		Growth	80,000
4	424	СР	W	Т	Dense Pack	195		No Growth	N/A
4	425	N/A	N/A	N/A	Control Inside Autoclave	219	Run 4 Full Exposure Control	No Growth	N/A

Table 3-1 (Continued)

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Drv)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
8	801	WB	D	В	Loose Pack - Horizontal	101		No Growth	N/A
8	802	WB	D	В	Loose Pack - Horizontal	102		No Growth	N/A
8	803	WB	D	В	Loose Pack - Horizontal	103		No Growth	N/A
8	804	WB	D	В	Loose Pack - Horizontal	104		No Growth	N/A
8	805	WB	D	В	Loose Pack - Horizontal	105		No Growth	N/A
8	806	CT	D	В	Loose Pack - Horizontal	106		No Growth	N/A
8	807	CT	D	В	Loose Pack - Horizontal	107		No Growth	N/A
8	808	CT	D	В	Loose Pack - Horizontal	108		No Growth	N/A
8	809	CT	D	В	Loose Pack - Horizontal	109		No Growth	N/A
8	810	CT	D	В	Loose Pack - Horizontal	110		No Growth	N/A
8	810	CT	D	В	Loose Pack - Horizontal	111	Duplicate	No Growth	N/A
8	811	WB	W	В	Loose Pack - Horizontal	112		No Growth	N/A
8	812	WB	W	В	Loose Pack - Horizontal	114		No Growth	N/A
8	812	WB	W	В	Loose Pack - Horizontal	113	Duplicate	Growth	<100
8	813	WB	W	В	Loose Pack - Horizontal	115		No Growth	N/A
8	814	WB	W	В	Loose Pack - Horizontal	116		No Growth	N/A
8	815	WB	W	В	Loose Pack - Horizontal	117		No Growth	N/A
8	816	CT	W	В	Loose Pack - Horizontal	118		No Growth	N/A
8	817	CT	W	В	Loose Pack - Horizontal	119		No Growth	N/A
8	818	CT	W	В	Loose Pack - Horizontal	120		No Growth	N/A
8	819	CT	W	В	Loose Pack - Horizontal	121		No Growth	N/A
8	820	CT	W	В	Loose Pack - Horizontal	122		No Growth	N/A
8	821	Couch	D	N/A	N/A	213		No Growth	N/A
8	822	Couch	D	N/A	N/A	214		No Growth	N/A
8	823	Couch	D	N/A	N/A	215		No Growth	N/A
8	824	Couch	D	N/A	N/A	216		No Growth	N/A
8	825	N/A	N/A	N/A	Control Inside Autoclave	220	Run 8 Full Exposure Control	No Growth	N/A

Table 3-1 (Continued)

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Drv)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
5	501	WB	W	N/A	Vertical - Uncut	159		No Growth	N/A
5	502	WB	W	N/A	Vertical - Uncut	160		No Growth	N/A
5	503	WB	W	N/A	Vertical - Uncut	161		No Growth	N/A
5	504	CT	W	N/A	Vertical - Cut	43		No Growth	N/A
5	505	CT	W	N/A	Vertical - Cut	44		No Growth	N/A
5	505	CT	W	N/A	Vertical - Cut	45	Duplicate	No Growth	N/A
5	506	CT	W	N/A	Vertical - Cut	46		No Growth	N/A
5	507	WB	D	N/A	Vertical - Uncut	130		No Growth	N/A
5	508	WB	D	N/A	Vertical - Uncut	131		No Growth	N/A
5	509	WB	D	N/A	Vertical - Uncut	132		No Growth	N/A
5	510	СТ	W	N/A	Vertical - Uncut	50		No Growth	N/A
5	511	СТ	W	N/A	Vertical - Uncut	51		No Growth	N/A
5	512	СТ	W	N/A	Vertical - Uncut	52		No Growth	N/A
5	513	СР	W	N/A	Vertical - Uncut	202		No Growth	N/A
5	514	СР	W	N/A	Vertical - Uncut	203		Growth	500
5	515	СР	W	N/A	Vertical - Uncut	204		Growth	470
5	516	СР	D	N/A	Vertical - Uncut	179		No Growth	N/A
5	517	СР	D	N/A	Vertical - Uncut	180		No Growth	N/A
5	518	СР	D	N/A	Vertical - Uncut	181		No Growth	N/A
5	518	СР	D	N/A	Vertical - Uncut	182	Duplicate	No Growth	N/A
5	519	CT	D	N/A	Vertical - Cut	60		No Growth	N/A
5	520	CT	D	N/A	Vertical - Cut	61		No Growth	N/A
5	521	СТ	D	N/A	Vertical - Cut	62		No Growth	N/A
5	522	CT	D	N/A	Vertical - Uncut	63		No Growth	N/A
5	523	СТ	D	N/A	Vertical - Uncut	64		No Growth	N/A
5	524	СТ	D	N/A	Vertical - Uncut	65		No Growth	N/A
5	525	N/A	N/A	N/A	Control Inside Autoclave	221	Run 5 Full Exposure Control	No Growth	N/A

Table 3-1 (Continued)

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Drv)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
6	601	WB	W	N/A	Vertical - Cut	147		Growth	<100
6	602	WB	W	N/A	Vertical - Cut	148		No Growth	N/A
6	602	WB	W	N/A	Vertical - Cut	149	Duplicate	No Growth	N/A
6	603	WB	W	N/A	Vertical - Cut	150		No Growth	N/A
6	604	CT	D	N/A	Vertical - Cut	17		No Growth	N/A
6	605	CT	D	N/A	Vertical - Cut	18		No Growth	N/A
6	606	CT	D	N/A	Vertical - Cut	19		No Growth	N/A
6	607	WB	D	N/A	Vertical - Cut	133		No Growth	N/A
6	608	WB	D	N/A	Vertical - Cut	134		No Growth	N/A
6	609	WB	D	N/A	Vertical - Cut	135		No Growth	N/A
6	610	CT	D	N/A	Vertical - Cut	24		No Growth	N/A
6	611	CT	D	N/A	Vertical - Cut	25		No Growth	N/A
6	612	CT	D	N/A	Vertical - Cut	26		No Growth	N/A
6	613	СР	W	N/A	Vertical - Cut	198		No Growth	N/A
6	614	СР	W	N/A	Vertical - Cut	199		No Growth	N/A
6	615	СР	W	N/A	Vertical - Cut	200		Growth	<100
6	616	CT	W	N/A	Vertical - Cut	30		No Growth	N/A
6	616	CT	W	N/A	Vertical - Cut	31	Duplicate	No Growth	N/A
6	617	CT	W	N/A	Vertical - Cut	32		No Growth	N/A
6	618	CT	W	N/A	Vertical - Cut	33		No Growth	N/A
6	619	СР	D	N/A	Vertical - Cut	184		No Growth	N/A
6	620	СР	D	N/A	Vertical - Cut	185		No Growth	N/A
6	621	СР	D	N/A	Vertical - Cut	186		No Growth	N/A
6	623	N/A	N/A	N/A	Control Inside Autoclave	222	Run 6 Full Exposure Control	No Growth	N/A
6	624	CT	W	N/A	Vertical - Cut	37		No Growth	N/A
6	625	CT	W	N/A	Vertical - Cut	38		No Growth	N/A
6	626	CT	W	N/A	Vertical - Cut	39		No Growth	N/A

3-9

Table 3-1 (Continued)

Run Number	Thermocouple Number	Material Type (WB = Wallboard, CT = Ceiling Tiles, CP = Carpet)	Moisture Content (W = Wet, D = Dry)	Depth in Bin	Packing Density/ Additional Notes	BI Test Pouch Number	Type of BI Control Sample	Growth/No Growth Result	Population Assay Result (CFU)
Control	N/A	N/A	N/A	N/A	N/A	205	Negative Control - Dry Wallboard	Growth	1,200,000
Control	N/A	N/A	N/A	N/A	N/A	206	Negative Control - Wet Wallboard	Growth	1,670,000
Control	N/A	N/A	N/A	N/A	N/A	207	Negative Control - Dry Ceiling Tiles	Growth	1,270,000
Control	N/A	N/A	N/A	N/A	N/A	208	Negative Control - Wet Ceiling Tiles	Growth	1,800,000
Control	N/A	N/A	N/A	N/A	N/A	209	Negative Control - Dry Carpet	Growth	1,300,000
Control	N/A	N/A	N/A	N/A	N/A	210	Negative Control - Wet Carpet	Growth	703,000
Control	N/A	N/A	N/A	N/A	N/A	211	Negative Control - Dry Empty Bag	Growth	990,000
Control	N/A	N/A	N/A	N/A	N/A	212	Negative Control - Wet Empty Bag	Growth	1,430,000
Control	N/A	N/A	N/A	N/A	N/A	223	Negative Control - Dry Empty Bag	Growth	843,000

N/A – Not applicable.

3.3.2.2 Temperature

All thermocouples were checked for quality using the procedure outlined in Section 6.3 of the QAPP prior to the test. All thermocouples met the acceptance criteria and were accurate to within \pm 0.7°F compared to a known reference thermometer. Reference testing was conducted at 275°F.

Thermocouples placed into each load were connected to a data logger through a 27-channel interface device. The thermocouple at each sample location was uniquely numbered using a system where the last two digits ran in a sequence from 01 to 24. Channels 25, 26, and 27 were used as spares or controls. Numbered thermocouples were connected in the same sequence to corresponding data logging channels. For example, thermocouple 101 was connected to channel 01, 102 to 02, and so forth. The instrumentation technician made the connections, which were verified by the ERG test director.

One thermocouple channel was used to monitor ambient conditions outside the autoclave to verify the data acquisition system was functioning properly. This temperature stayed relatively constant throughout each run, varying between 60 and 75°F. A thermocouple also was mounted near the top of one of the autoclave bins in each run, fully exposed to autoclave conditions. These data tracked closely with the process temperature measurements for all runs except Run 2. The thermocouple reading for the fully exposed autoclave temperature in Run 2 (thermocouple 225) suddenly dropped approximately 20°F, 18 minutes into cycle. After the autoclave cycle was complete, the thermocouple and corresponding BI test pouch were found to have fallen from their mount on the autoclave bin wall into the bulk of BDR mass being tested. For all subsequent runs, the thermocouple was mounted using a c-clamp rather than duct tape, and a second control thermocouple was placed near the bottom of the bin so that fully exposed thermocouples were placed near the top and toward the bottom of an autoclave bin. Note that a fully exposed control BI test pouch was only placed next to the top control thermocouple. Fully exposed control thermocouple readings were consistent with process temperature readings on all subsequent runs.

During the runs, thermocouples 102, 401, and 423 failed and either stopped providing a signal or sent negative temperature readings. Significant signal noise was also observed in thermocouples 108, 117, 118, 121, and 814. During Run 1, condensate from steam that traveled inside the sheathed thermocouple wire collected on the thermocouple connectors outside the autoclave. The condensate collecting within the connectors likely caused the signal noise and in some cases failure of the thermocouples in Run 1. After Run 1, the connectors were inverted to force the condensate to drip off the wires instead of collecting in the connectors, which eliminated most of the signal noise and failure problems. Of the 162 time/temperature data series, 156 were collected satisfactorily, resulting in 96 percent complete data. Therefore, the acceptance criteria of at least 80 percent of the data being collected satisfactorily was met.

No data from the three thermocouples that failed were used for the analyses in this report. Data from the five thermocouples with significant noise were used. Most of the noise resulted in abrupt temperature spikes or dips of less than 50°F. However, there were two data spikes for thermocouple 118 where the temperature reading more than doubled for approximately 20 seconds. This is characteristic of no signal being received by the data logger for a short period. Data from the data point immediately preceding the spikes were extrapolated and used for data analyses instead of the temperature spike data for these two instances for thermocouple 118. All other temperature data were used as recorded.

3.3.2.3 Test Conditions

The ERG test engineer recorded the test conditions on log sheets as identified in the QAPP. The ERG test engineer and ERG test director verified and signed all log sheets for each run.

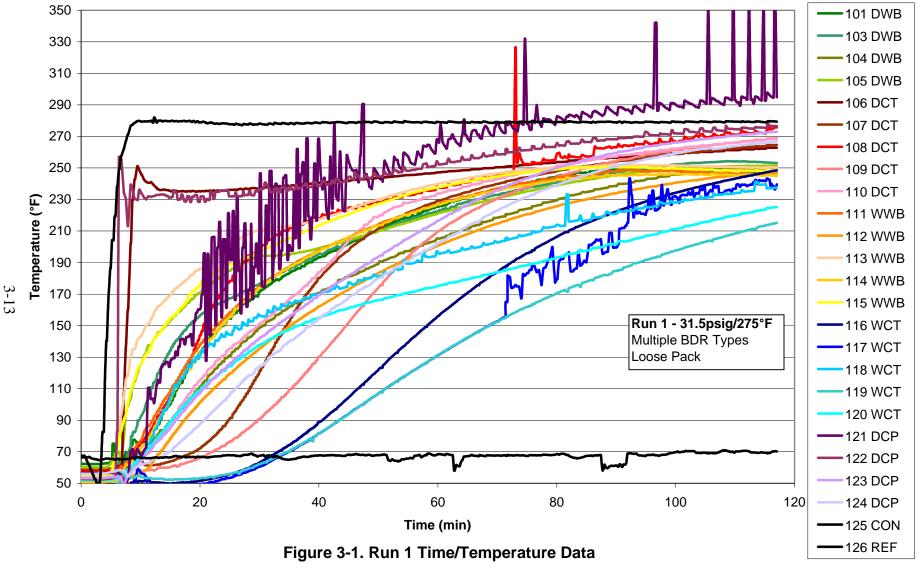
3.3.2.4 BI Test Strip Results

Raven Biological Laboratories, Inc. analyzed the BI test strips. All samples were successfully analyzed, providing a100 percent complete data set.

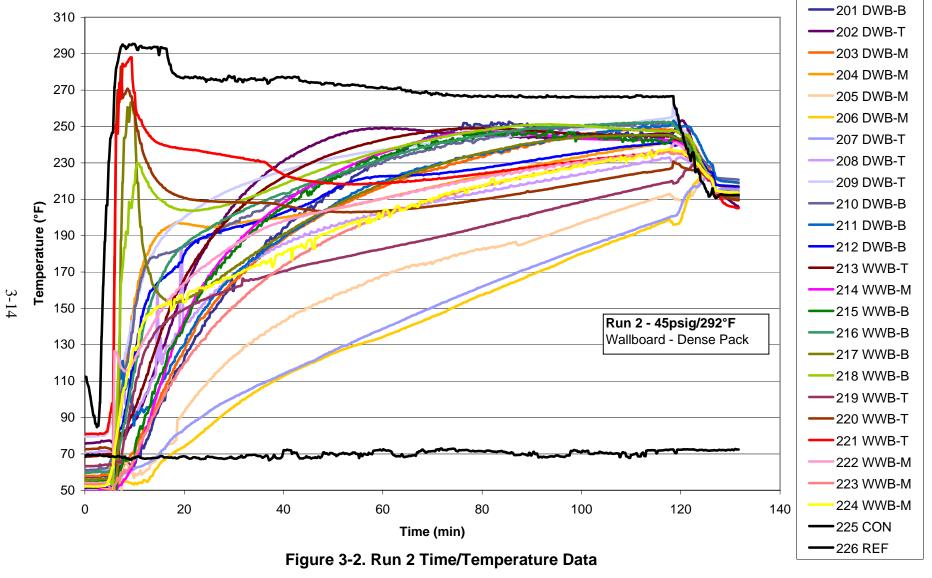
Three sets of control BI pouches were analyzed. First, two duplicate sample pouches were placed within each test run, adjacent to the sample pouch it was duplicating. Of the 12 duplicate pouches, 10 yielded the same results as the corresponding sample pouches (i.e., growth was found in both in one case and no growth was found in both in nine cases). However, at two of the sample points (thermocouples 217 and 812) the growth/no-growth results for the duplicates did not match (i.e., the 'A' strip for the duplicate indicated growth and the 'A' strip for the sample did not). The 'B' strips for the duplicates were assayed and no viable survivor population was found (<100 CFU), consistent with the A strip of the original sample. These data suggest that, in some cases, a growth indication alone may be a false positive result (2 of the 12 cases measured). However, the growth/no-growth indication coupled with the BI assay data is a reliable measure of sterilization and spore viability.

Additionally, nine blind control samples were analyzed that were not exposed to autoclave conditions, but in all other respects handled the same as other BI test pouches. These nine controls all yielded positive results for growth, and the assay data confirm that no significant reduction in viable spores was caused by the handling, packaging, and shipping of the BI pouches.

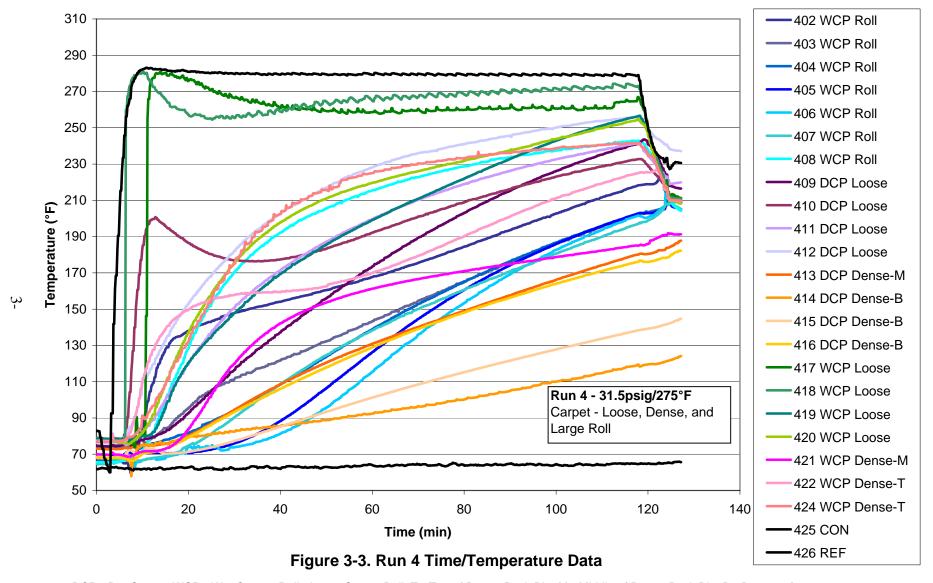
Finally, one blind control test pouch was autoclaved in each run, not embedded in any building material and exposed fully to autoclave conditions. These controls for all runs except Run 2 yielded negative results for growth. Upon analyzing the assay data for the Run 2 control, only a 10⁴ reduction in viable spores was achieved. As mentioned previously, the thermocouple and corresponding BI test pouch for Run 2 fell from their mount on the autoclave bin wall and became embedded in the BDR mass in Run 2. This caused the BI test pouch not to be fully exposed to the autoclave conditions and is likely the cause of the remaining spore viability. No growth was observed in every other quality assurance sample fully exposed throughout the test.



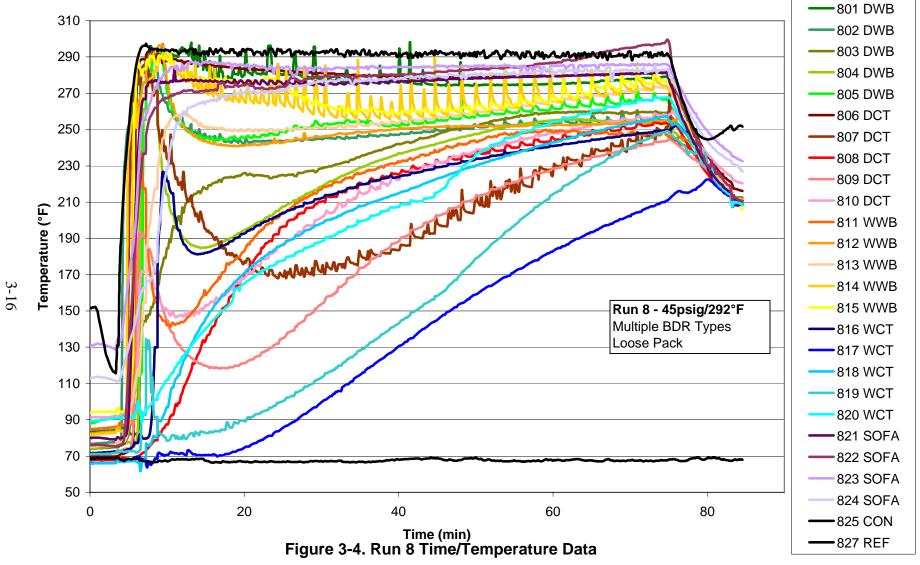
DWB - Dry Wallboard; WWB - Wet Wallboard; DCT - Dry Ceiling Tiles; WCT - Wet Ceiling Tiles; DCP - Dry Carpet; CON - Fully Exposed Control; REF - Exterior Reference Temperature



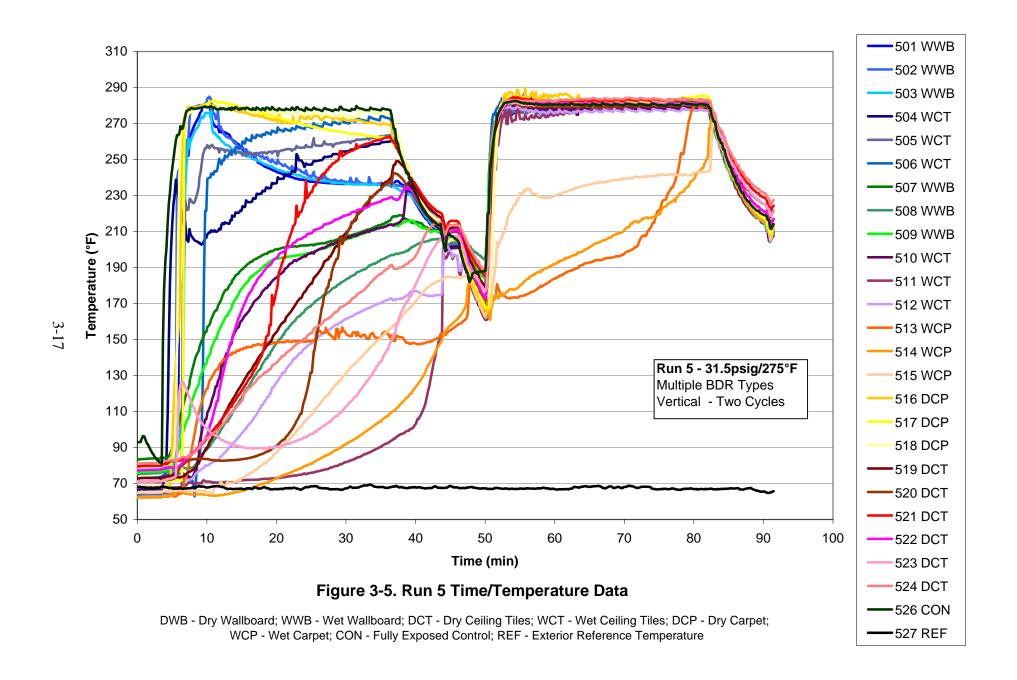
DWB - Dry Wallboard; WWB - Wet Wallboard; T - Top of Dense Pack Bin; M - Middle of Dense Pack Bin; B - Bottom of Dense Pack Bin CON - Fully Exposed Control; REF - Exterior Reference Temperature

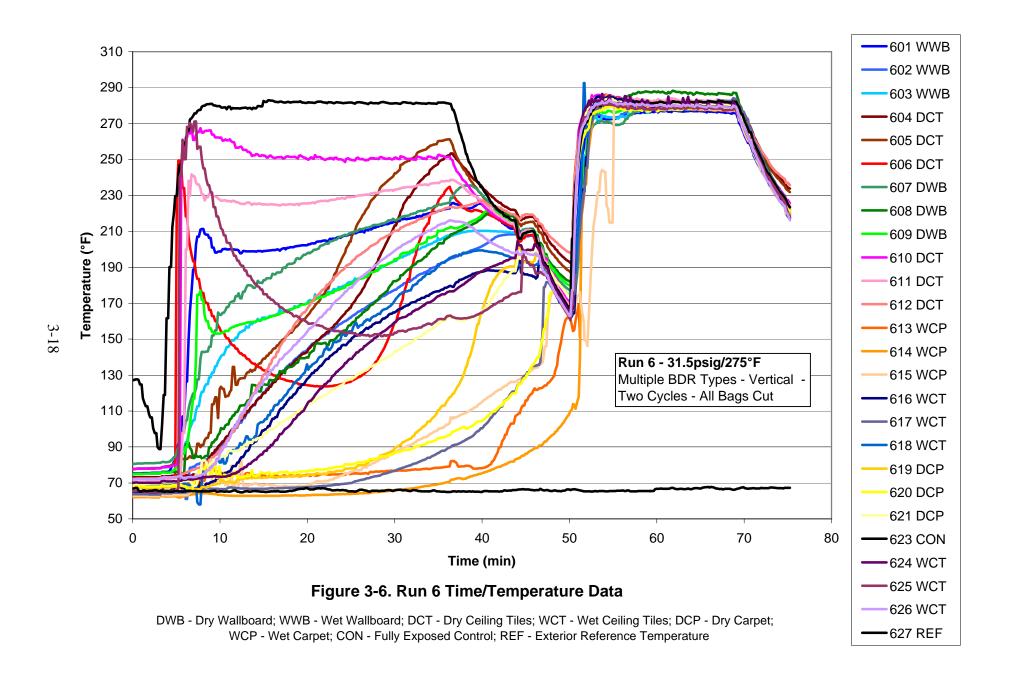


DCP - Dry Carpet; WCP - Wet Carpet; Roll - Large Carpet Roll; T - Top of Dense Pack Bin; M - Middle of Dense Pack Bin; B - Bottom of Dense Pack Bin CON - Fully Exposed Control; REF - Exterior Reference Temperature



DWB - Dry Wallboard; WWB - Wet Wallboard; DCT - Dry Ceiling Tiles; WCT - Wet Ceiling Tiles; CON - Fully Exposed Control; REF - Exterior Reference Temperature





4.0 DISCUSSION

As discussed previously, the following variables were identified as having a potential impact on sterilization capability:

- 1. Item type;
- 2. Autoclave packing density (i.e., loose packing versus dense packing);
- 3. Moisture content of autoclaved materials;
- 4. Autoclave temperature/pressure; and
- 5. Time in autoclave.

During the test, three additional factors were identified as potentially influencing sterilization capability:

- 1. Positioning sample bags of BDR vertically instead of horizontally;
- 2. Cutting open the bags of BDR to facilitate steam penetration; and
- 3. Running two shorter process cycles in sequence instead of one long cycle.

One additional factor that may affect sterilization not investigated in this study was the packaging technique. BDR was cut up, double bagged in 1.8 mil autoclave bags, and goose-necked closed with duct tape, to mimic BDR generated from a likely disposal incident. Other packaging techniques (e.g., bag/container type, bag thickness, quantity of BDR per bag, and sealing method) that may also influence sterilization ability were not evaluated.

This section first discusses the impact of the observed time/temperature profiles on BDR sterilization, measured using the BI growth/no-growth and assay results. The section then presents how each of the variables above affected the temperature profile and associated sterilization results.

4.1 Time and Temperature Effect on Sterilization

Figures 4-1 through 4-3 present the time and temperature affect on sterilization for Runs 2, 4, and 5. All figures are located at the end of this section. On each figure, the time/temperature profile is plotted, and the lines are color coded to indicate whether the

associated BI data indicated viable spores or no viable spores. A viable spore designation is used if growth was found in both the growth/no-growth test and the assay analysis. Sterilization or a no viable spore designation is used if no growth was found in the growth/no-growth test with an 10^6 initial BI population. In a limited number of cases, the growth/no-growth test indicated a positive result; however, no quantifiable population was measured by the subsequent assay analysis (reported result of <100 CFU). These data series are labeled as indeterminate.

No figures are provided for Runs 1, 8, and 6 because no viable spores were found in these runs. The temperature profiles for these runs can be viewed on Figures 3-1, 3-4, and 3-6, respectively. Each of these runs contained loose pack BDR materials, processed at different conditions.

The spores were sterilized in all cases where the target of 15 minutes at 250°F was achieved. While spores were also sterilized in several instances below this target, 15 minutes at 250°F was required to ensure sterilization. The effect of each variable on sterilization is discussed in the following subsections.

4.2 Item Type and Moisture Content

The temperature profiles for Runs 1, 8, 5, and 6, presented in Figures 4-4 through 4-7, respectively, show the influence of item type on temperature profile. Within each of these runs, different item types were autoclaved under the same conditions. An average data series is provided for each item type on each figure. The average data series were calculated as the arithmetic average of the temperature at each time T, at every sampling location of that type. For example, in Run 1, there were five wet ceiling tile sampling locations. The temperature plotted for the wet ceiling tile series at T=20 minutes is the average of the temperatures at each of the five wet ceiling tile locations at T=20 minutes. Where averages were calculated, the number of sample points averaged is presented next to each series.

As shown on the figures, dry carpet and dry ceiling tiles heated more rapidly than wet carpet and wet ceiling tiles, respectively. Dry wallboard and wet wallboard heated at approximately the same rate in three of the four runs where comparison can be made (Figures 4-

4, 4-5, 4-7). In Run 5 (Figure 4-6), the wet wallboard heated significantly faster. These differences are believed to be functions of the moisture content of each material. The difference between dry and wet carpet and ceiling tile results are likely due to the significant water absorbing-capacity of carpet (53 percent increase in weight when wet) and ceiling tiles (34 percent increase in weight when wet). The significant water content of the wet carpet and ceiling tiles increases the thermal load needed to boil the water and heat the material in the autoclave and may also decrease steam penetration.

Wallboard does not absorb as much water when wet (9 percent increase in weight when wet). This would explain the relatively similar results for wet and dry wallboard observed on Figures 4-4, 4-5, and 4-7.

With respect to differing item types, wet wallboard heated faster than wet ceiling tiles, which heated faster than wet carpet. This relationship was observed in all runs and is consistent with the relative water-absorbing capacity of each material, as discussed above. When moisture content is eliminated as a variable and dry BDR items are compared to each other, there is no apparent trend. For example, dry carpet heated fastest in Run 1, but slower than dry ceiling tiles and dry wallboard in Run 6. Similarly, dry ceiling tiles heated fastest in Run 6, but slower than dry wallboard and dry carpet in Run 5. These observations suggest that trends and differences in heating rates between BDR item types depends primarily on the moisture content of wet items, and not on the BDR material itself.

The sofa, tested dry, heated more rapidly than wallboard and ceiling tiles in the one run where it was tested (Figure 4-5). If it had been saturated with water, the results may have been significantly different, based on the findings for ceiling tiles and carpet.

4.3 Autoclave Packing Density and Location

The effect of autoclave packing density is best isolated from other variables by examining the data for Runs 2, 4, and 8. Wet and dry wallboard were tested in both loose pack (one layer of bags) and dense pack arrangement (approximately four layers of bags) in Runs 2 and 8, respectively. Both runs were conducted at 45 psig (292°F). Figure 4-8 presents average

time/temperature profile data for each set of conditions. Carpet was tested in both a loose pack and dense pack arrangement in Run 4 at 31.5 psig (275°F); Figure 4-9 presents average time/temperature profile data. As shown by these figures, loose pack items heat significantly faster than dense pack. Most of the dense pack sample points never achieved the target temperature of 250°F for 15 minutes, and resulted in significant remaining spore viability (see Figures 4-1 and 4-2). The majority of the positive growth results found during the test were in the dense packing configuration.

The temperature profile within the thermal mass was investigated using data from Run 2. Figure 4-10 presents average data from dense pack wallboard in Run 2 at varying levels within the mass. Top layer data points are from thermocouples in bags at the top of the mass, exposed to the autoclave conditions; middle layer data points are from bags in between other bags; and bottom layer data point are from bags touching the bottom of the bin. As shown by these data, the bags at the bottom of the bin heated fastest, indicating conduction through the metal bin may be a factor in heating the BDR. However, remaining viable spores were found in all three layers of densely packed material.

Selected wallboard bags were examined to investigate the temperature profile within the 3-sample bags. Figure 4-11 presents two examples, comparing the temperature profile within a dry loose pack wallboard bag and a dry dense pack, middle layer wallboard bag. As shown in the loose pack bag, while the center of the bag generally heated more slowly, all three temperature readings gradually converge, and the spores were all sterilized at all three locations. However, there was not enough time for the bag in the dense pack configuration to reach a sterilization temperature. Sterilization was only achieved between the first and second sheet.

Figure 4-12 presents the temperature profile within selected loose pack ceiling tile bags. Similarly, the center of the bags heated slowest. However, all sample points came up to temperature and all spores were sterilized in the loose pack arrangement.

Temperature and Pressure

As mentioned previously, autoclave temperature and pressure are related variables, as the autoclave is designed to operate at saturated steam conditions. Two conditions were investigated: 31.5 psig/275°F, the typical operating pressure of the autoclave, and 45 psig/292°F, the maximum operating pressure of the autoclave. The effect of autoclave temperature and pressure is best isolated from other variables by examining the data from Runs 1 and 8. Loose pack, wet and dry wallboard and ceiling tiles were processed in Run 1 at 31.5 psig/275°F and in Run 8 at 45 psig/292°F. Figure 4-13 compares the wallboard data collected for Run 1 versus Run 8, and Figure 4-14 compares the ceiling tile data for both runs. For both materials, the higher temperature and pressure accelerated the BDR heating process significantly. However, all BIs from both runs exhibited no growth. Run 1 at the lower temperature was conducted for 120 minutes while Run 8 at the higher temperature was terminated after 75 minutes.

4.5 **Packing Orientation**

Materials were tested both lying horizontally and positioned vertically. The vertical packing arrangement was only tested in loose packing configuration using two 40-minute autoclave cycles in sequence. The packing orientation variable is best isolated by comparing wallboard and ceiling tile data between Runs 1 and 5 and carpet data between Runs 4 and 5. Figures 4-15 through 4-17, respectively, present the average data for these runs for each item type. In reviewing these figures, only data for the first 40 minutes should be considered for comparison purposes, as that is when the postvacuum cycle began during Run 5, which is different from Runs 1 and 4. Accounting for the different starting temperatures between the runs, the data appear variable and no firm conclusions can be drawn about the influence of packing orientation on autoclave performance.

4.6 Open Bags

Runs 5 and 6 were performed under the same conditions, except that two of the eight bags tested were sliced open prior to autoclaving in Run 5 and all of the bags were sliced open prior to autoclaving in Run 6. Figures 4-18, 4-19, and 4-20 present the average data from these runs, comparing results for cut and uncut bags for wallboard, ceiling tiles, and carpet, respectively. The data available to make this comparison are limited and somewhat variable. In most cases, the data presented are for three sample locations within one bag of BDR. As seen on Figure 4-18, wet wallboard in an uncut bag heated most rapidly. On Figure 4-19, ceiling tiles in cut bags heated most rapidly. On Figure 4-20, dry carpet in an uncut bag heated most rapidly, but wet carpet in an uncut bag heated most slowly. This uncut bag of wet carpet was the only bag in Runs 5 or 6 to contain biological indicators with surviving spores. All other biological indicators from these runs exhibited no surviving spores.

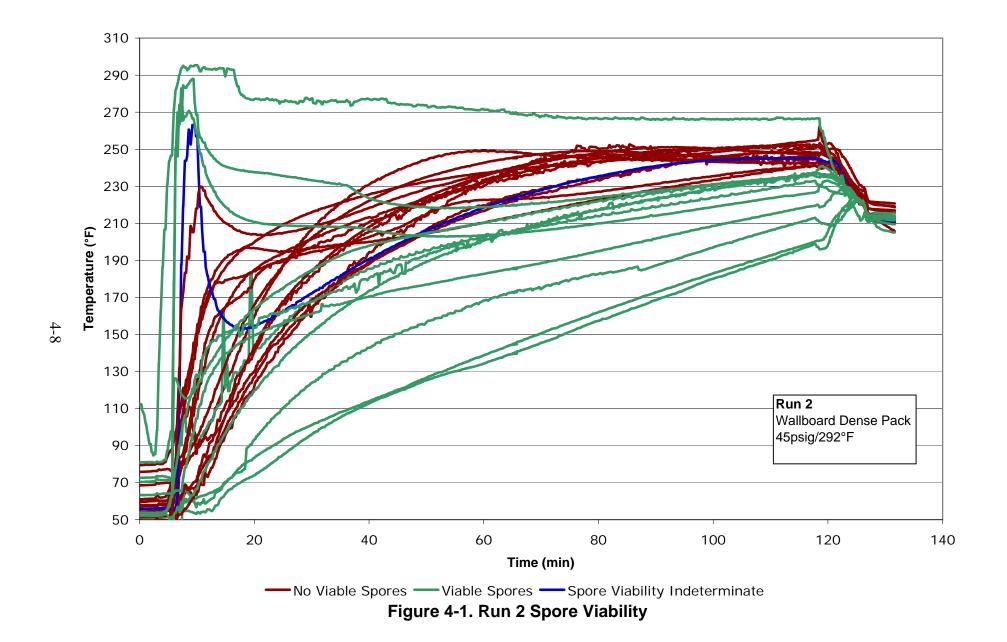
It is worth noting that even bags that were not cut open prior to autoclaving had a tendency to rupture in the autoclave when subjected to the pressure differentials and heat of the autoclave cycle.

Based on these data, we cannot draw any firm conclusions regarding the impact of cutting bags open prior to autoclaving.

4.7 Two Sequential Cycles

As illustrated in Figures 3-5 and 3-6, conducting two standard autoclave cycles in sequence proved to be quite effective in bringing BDR items up to the full autoclave temperature rapidly after steam is applied during the second cycle. We believe that applying a vacuum between the first and second cycles is what is particularly effective about this approach. The first cycle acts to preheat the material, although it is likely that the initial contact between the steam and the BDR material results in immediate condensation, filling pore spaces within the material. Consequently, steam supplied later in the cycle does not penetrate well into the material, and the material only slowly heats due to free convection and conduction from the bin walls. Applying a vacuum prior to the second cycle likely pulls the condensate away from the

material, and when steam is subsequently applied, it penetrates well into the material, which quickly rises to the full autoclave temperature. In fact, Run 6 was terminated early because all BDR materials had been over 270°F for 15 minutes well before the second cycle was scheduled to be completed. When subjected to two autoclave cycles in sequence, all biological indicators except for those in the one bag of wet carpet in Run 5 exhibited no surviving spores. Two autoclave cycles did not consistently result in no-growth for BI test strips placed in wet carpet. It may be necessary to further process wet carpet beyond two cycles to effectively sterilize it.



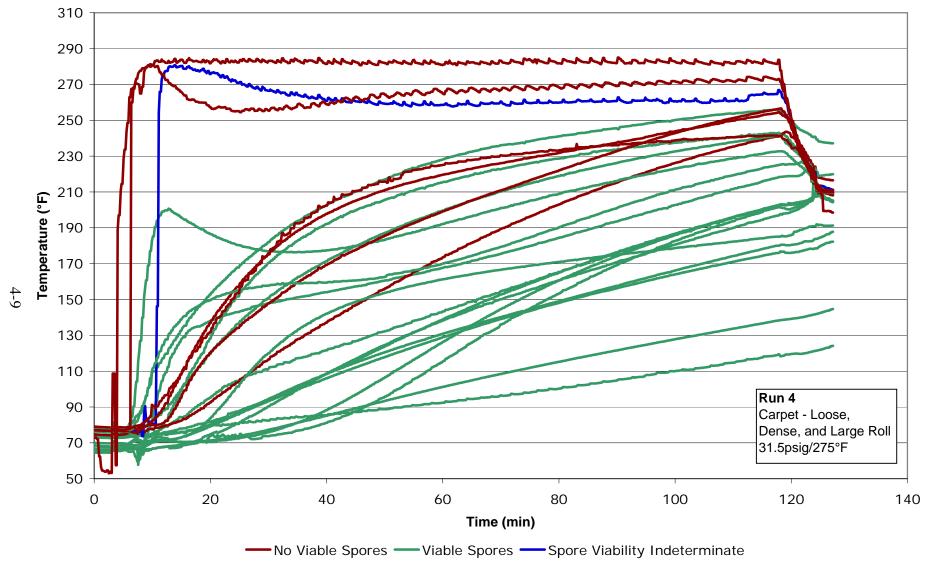


Figure 4-2. Run 4 Spore Viability

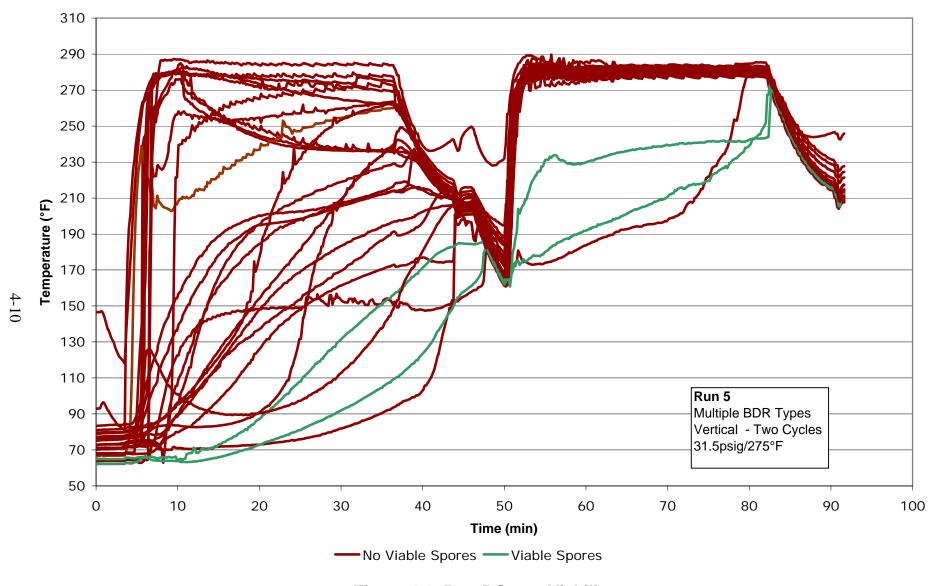


Figure 4-3. Run 5 Spore Viability

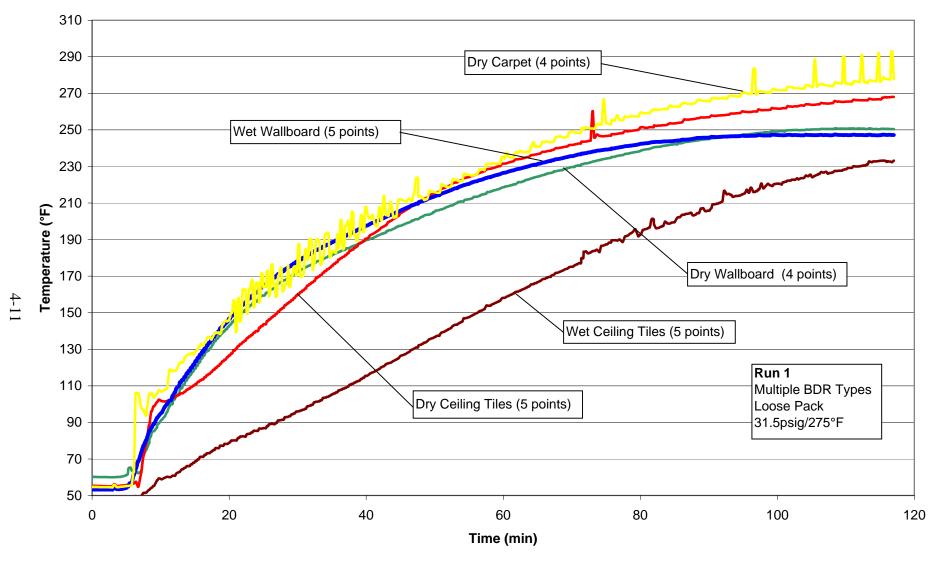


Figure 4-4. Run 1 Moisture Content and Item Type Comparison

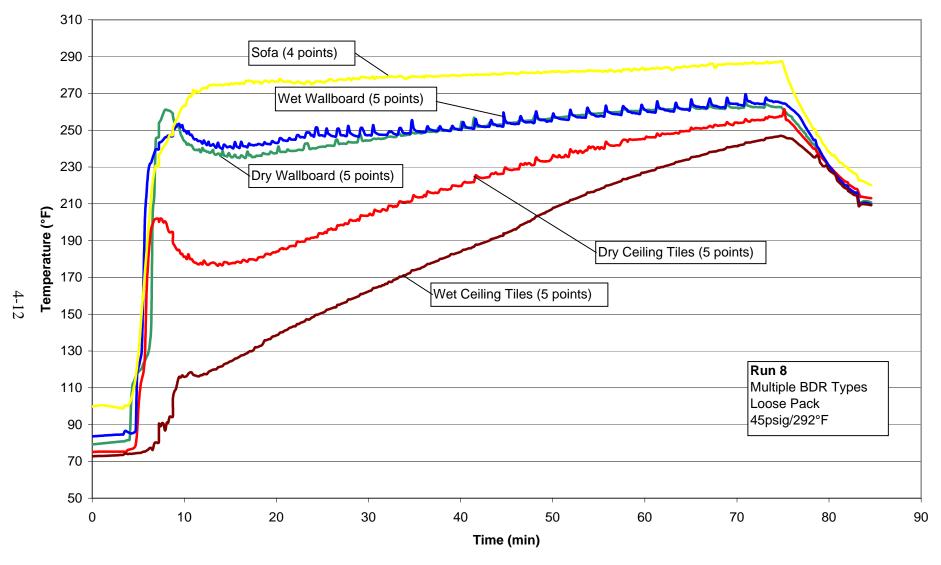


Figure 4-5. Run 8 Moisture Content and Item Type Comparison

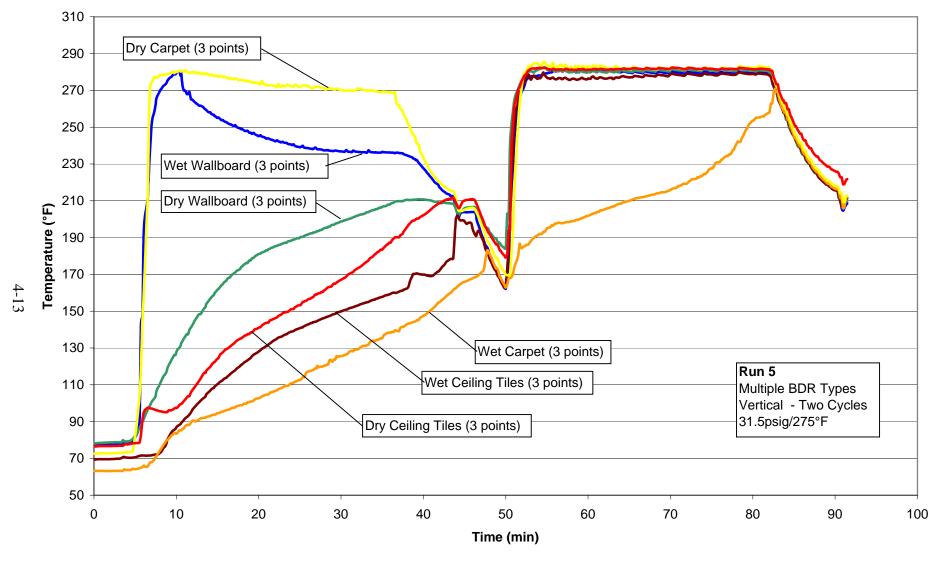


Figure 4-6. Run 5 Moisture Content and Item Type Comparison (Uncut Bags Only)

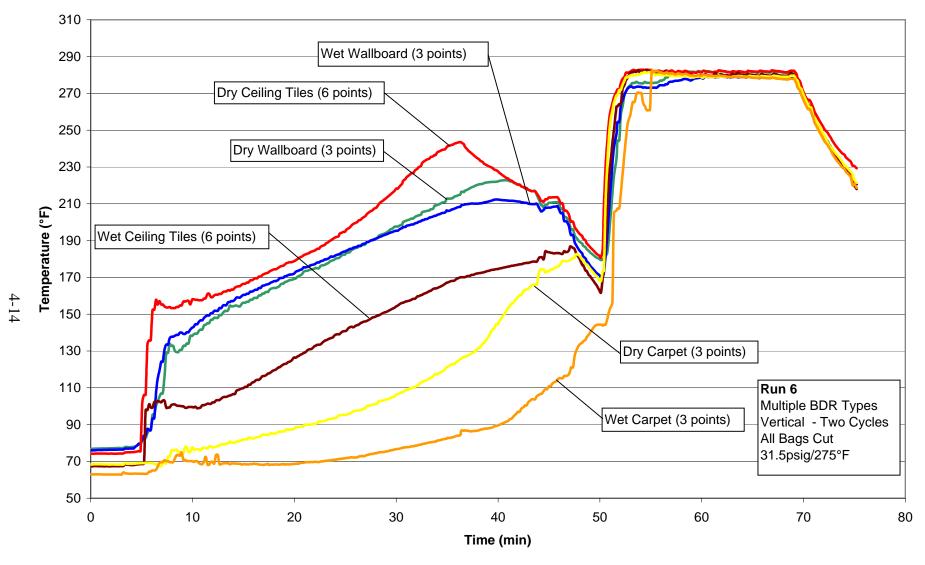


Figure 4-7. Run 6 Moisture Content and Item Type Comparison

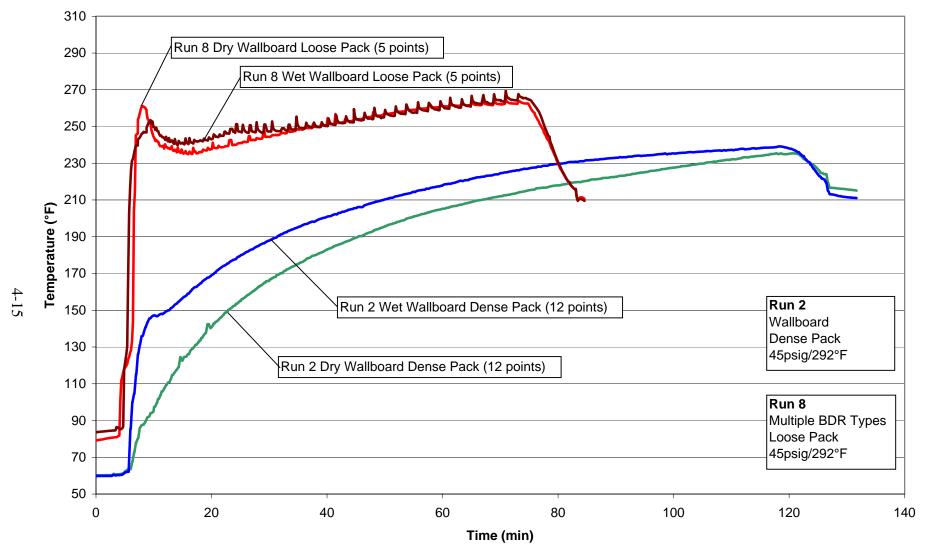


Figure 4-8. Wallboard Packing Density Comparison

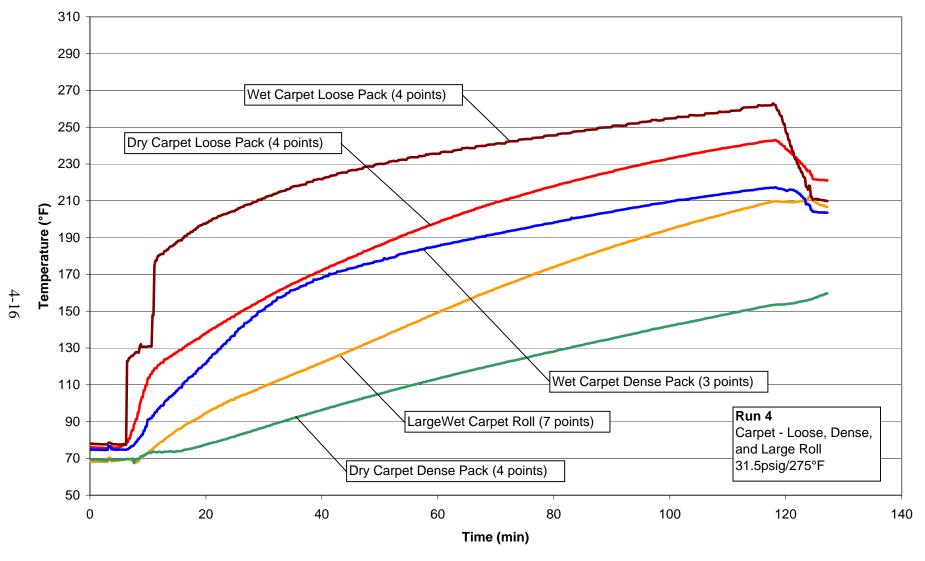


Figure 4-9. Carpet Packing Density Comparison

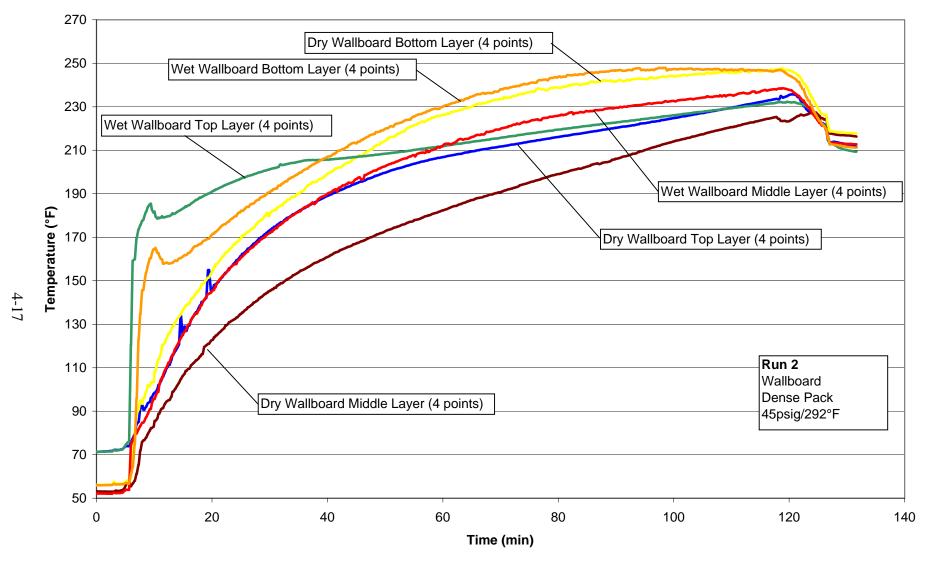


Figure 4-10. Run 2 Dense Packing Layer Comparison

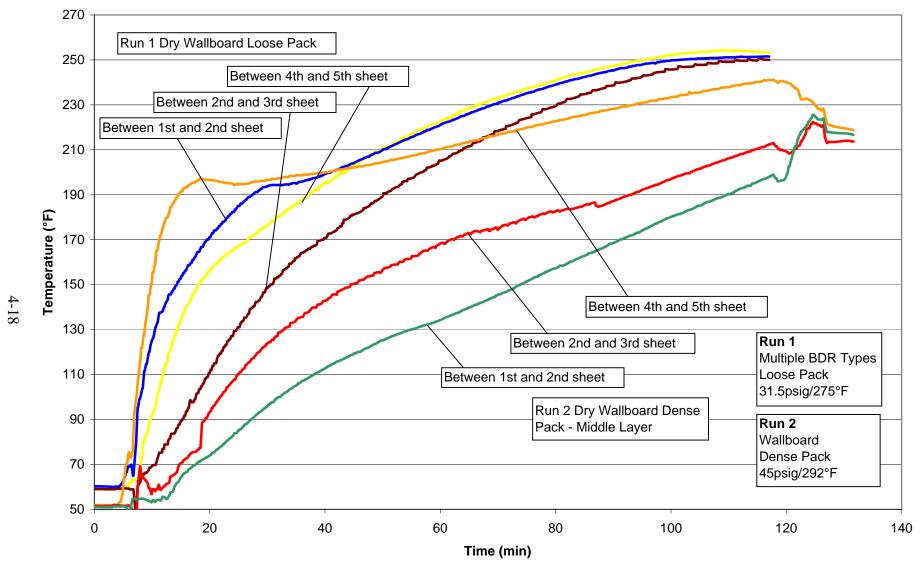


Figure 4-11. Comparison of Sample Points Within Selected Wallboard Bags

Note: 1st sheet was always on top in the bins.

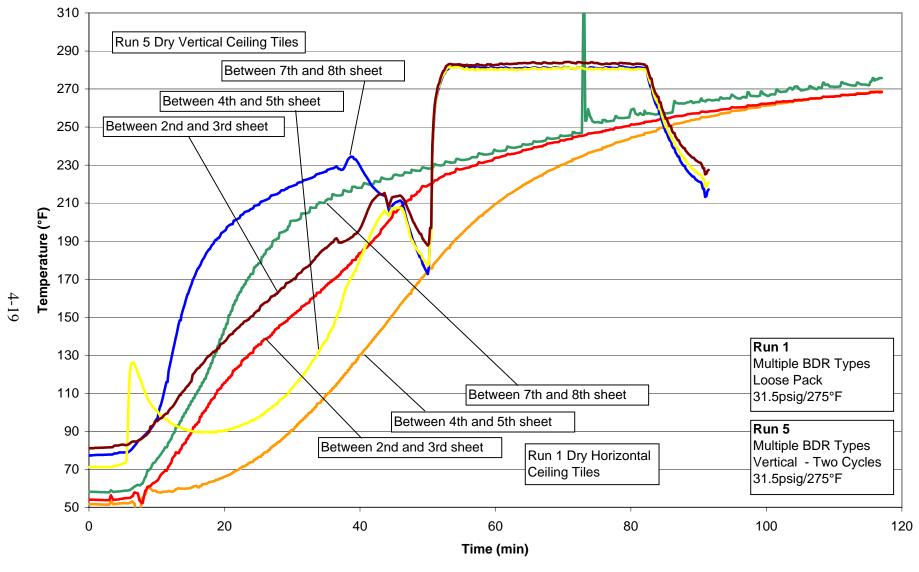


Figure 4-12. Comparison of Sample Points within Selected Ceiling Tile Bags

Note: 1st sheet was always on top in the bins.

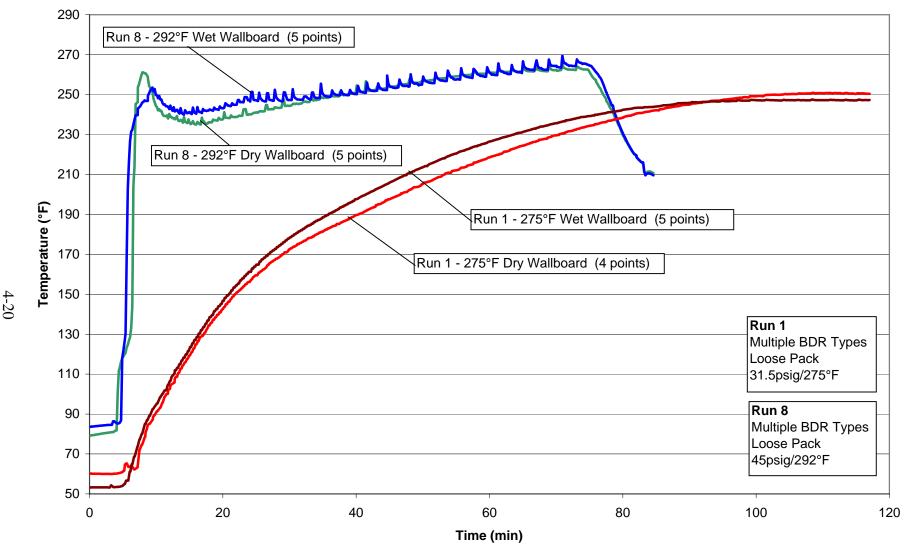


Figure 4-13. Autoclave Temperature Comparison for Wallboard

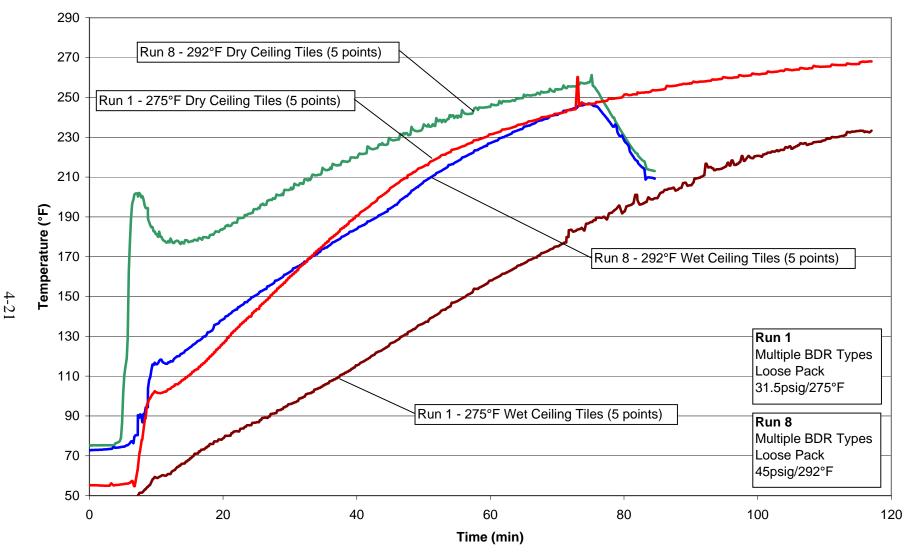


Figure 4-14. Autoclave Temperature Comparison for Ceiling Tiles

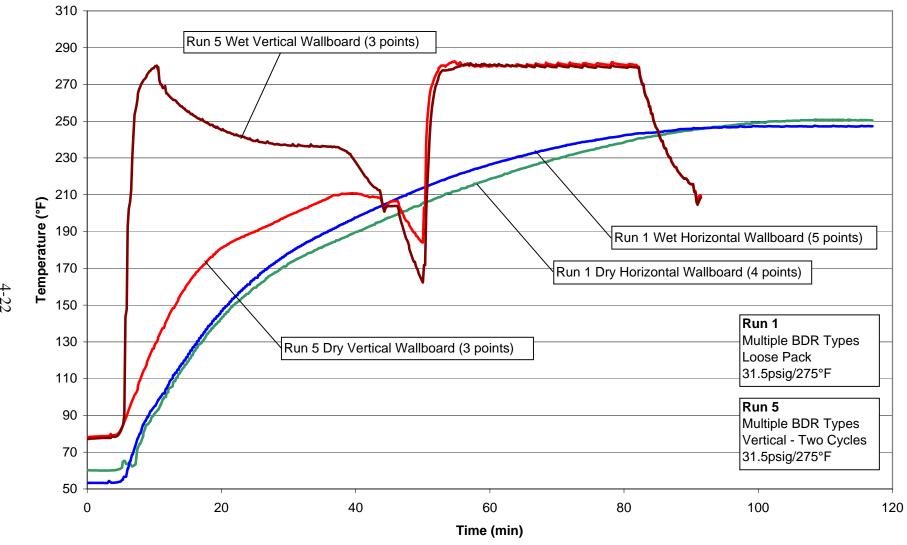


Figure 4-15. Horizontal Versus Vertical Packing Orientation for Wallboard

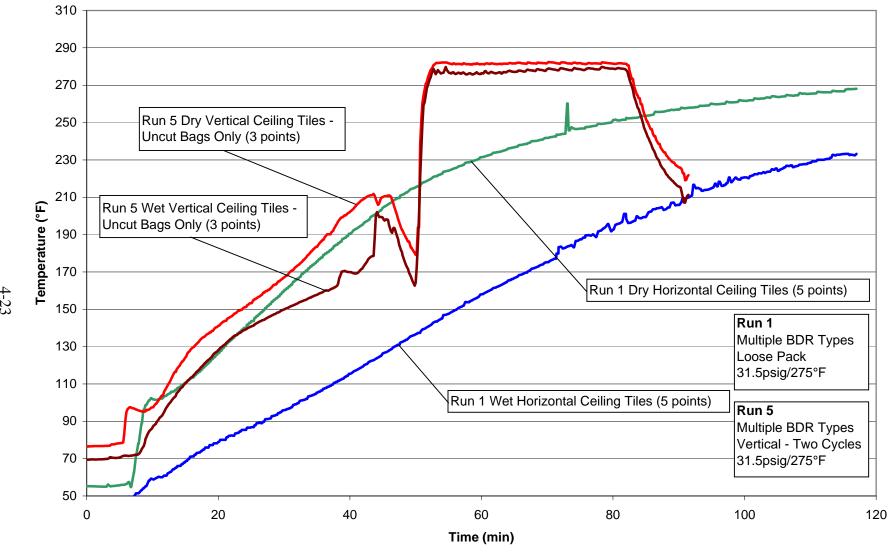


Figure 4-16. Horizontal Versus Vertical Packing Orientation for Ceiling Tiles

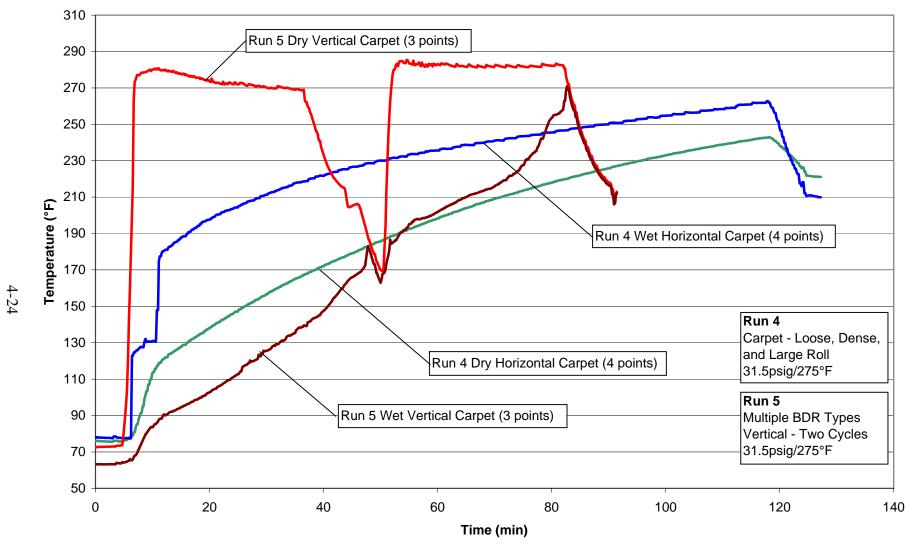


Figure 4-17. Horizontal Versus Vertical Packing Orientation for Carpet

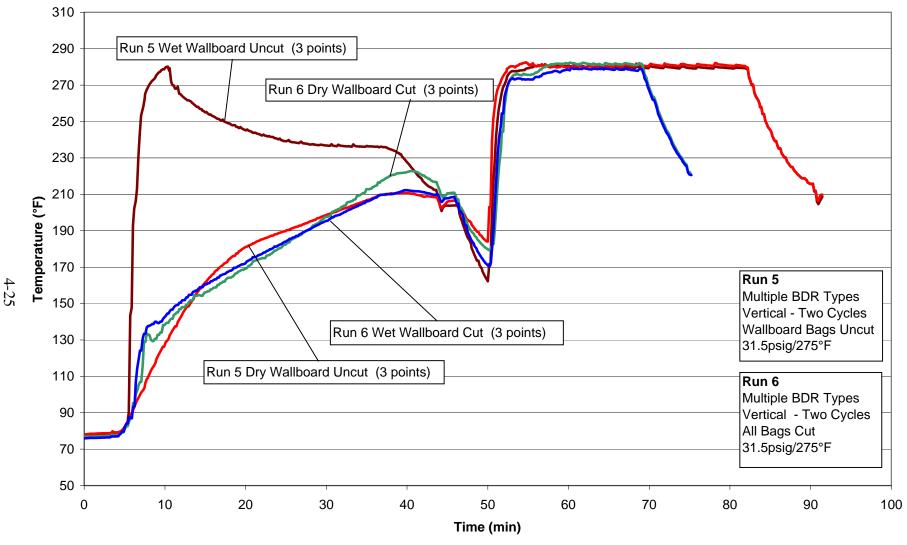


Figure 4-18. Cut Versus Uncut Wallboard Bags

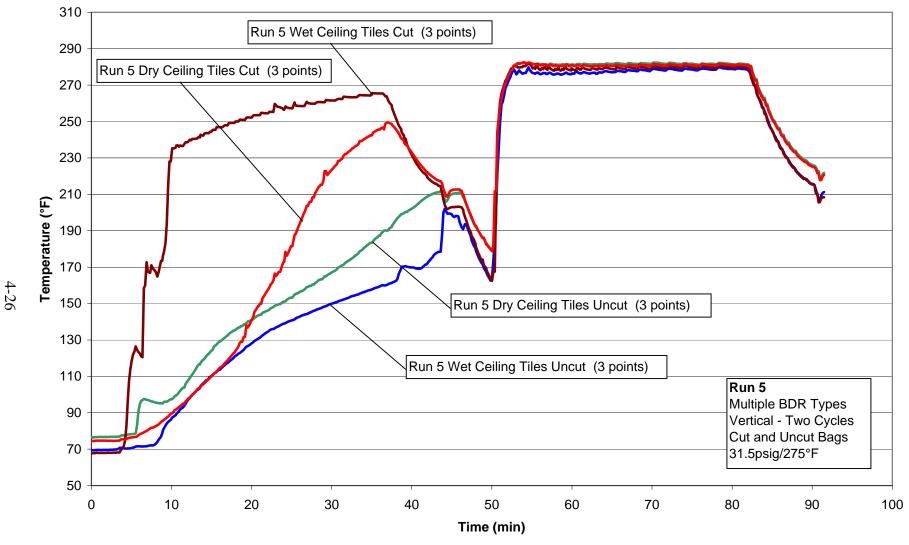


Figure 4-19. Cut Versus Uncut Ceiling Tile Bags

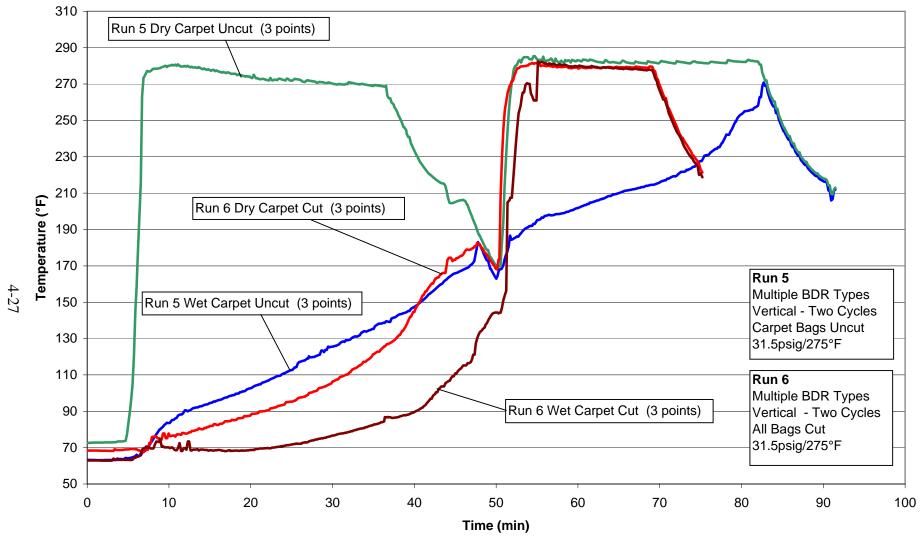


Figure 4-20. Cut Versus Uncut Carpet Bags

5.0 CONCLUSIONS

Based on variables evaluated in this study, the following conclusions can be drawn regarding processing of BDR material in a commercial-scale autoclave. Conclusions regarding sterilization are based on a finding of no growth, using 10⁶ population BI test strips.

General Conclusions

- Achieving an internal BDR material temperature of 250°F or higher for 15 minutes or longer destroyed all biological indicators. The following approaches were most effective in achieving this: using a loose packing configuration, processing dry BDR material, establishing higher autoclave operating temperature and pressure, and running multiple autoclave cycles in sequence.
- Bagged wallboard (wet or dry), ceiling tiles (wet or dry), and dry carpet can be
 effectively sterilized under appropriate time, temperature, and packing conditions.
 Time, temperature, and packing requirements are provided below.
- Dry upholstered furniture can be effectively sterilized. No conclusions are drawn regarding wet upholstered furniture.

Time, Temperature, and Pressure Effects

- An autoclave cycle of 120 minutes at 31.5 psig/ 275°F effectively sterilized wallboard, ceiling tiles, and dry carpet, when loaded in the autoclave as described below.
- An autoclave cycle of 75 minutes at 45 psig/ 292°F effectively sterilized wallboard and ceiling tiles, when loaded in the autoclave as described below.
- Two standard autoclave cycles of 40 minutes and 31.5 psig/ 275°F run in sequence effectively sterilized wallboard, ceiling tiles, and dry carpet, when loaded as described below. Available data suggest the second cycle can be shortened to 20 minutes. Two autoclave cycles did <u>not</u> consistently result in no growth for BI test strips placed in wet carpet. It may be necessary to further process wet carpet beyond two cycles for effective sterilization. It appears that evacuating the autoclave between the first the second cycle is critical, allowing the second cycle to successfully sterilize the BDR.

Autoclave Loading

Bags of BDR material should be placed in the autoclave so that all surfaces are
exposed to autoclave conditions. Bags lying flat against a metal surface, such as
the base of an autoclave bin, are considered to be fully exposed to autoclave
conditions.

- Bags of BDR material stacked or nested such that they are not fully exposed to autoclave conditions may not be reliably sterilized under the conditions tested.
- Bags of ½ inch wallboard slabs up to 5 layers thick and 5/8 inch ceiling tiles up to 9 layers thick can be effectively sterilized under the time, temperature, and packing density conditions described above.
- Dry commercial grade carpet rolls formed from pieces 26 inches wide and 20 feet long can effectively sterilized under the time, temperature, and packing density conditions described above.

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Appendix A PHOTOGRAPHIC LOG



Photo 1. Healthcare Environmental's Oneonta, New York Facility



Photo 2. Wallboard Size Reduction



Photo 3. Stacks of Size Reduced Wallboard and Ceiling Tiles



Photo 4. Submersing Wallboard Sheets



Photo 5. Wallboard on Dry Rack



Photo 6. Assembled Sample Point



Photo 7. Sample Point (Thermocouple Paired with a BI Test Pouch)



Photo 9. Palletized Bags of Ceiling Tiles



Photo 11. Carpet Wetting

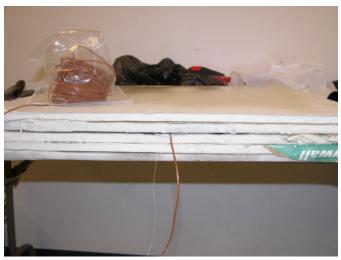


Photo 8. Sample Point Between Sheets of Drywall



Photo 10. Bulk Quantity of Used Commercial Carpet



Photo 12. Sample Point within Carpet



Photo 13. Water Draining out of Assembled Carpet Roll



Photo 14. Assembled Bags of Small Carpet Rolls



Photo 15. Assembled Large Carpet Rolls



Photo 16. Sofa Wrapping



Photo 17. Empty Autoclave



Photo 18. Empty Autoclave Bin



Photo 19. Autoclave Bins on Transfer Cart



Photo 20. Bins Loaded into Autoclave



Photo 21. Flange Port



Photo 22. Fabricated Flange Port to Allow Thermocouple Wires to Pass Through



Photo 23. Connectors Not Inverted Allowing Condensate to Collect in the Connectors



Photo 24. Connectors Inverted to Allow Condensate to Drip Off the Wires



Photo 25. Data Acquisition System



Photo 26. Pallets of BDR Material



Photo 27. Loose Pack Wallboard Bin



Photo 28. Wallboard Bags After Autoclaving



Photo 29. Dense Pack Wallboard Bin



Photo 30. Loose Pack Ceiling Tile Bin



Photo 31. Loose Pack Carpet Bin



Photo 33. Dense Pack Carpet Bin



Photo 35. Vertical Orientation



Photo 32. Loose Pack Carpet Bin After Autoclaving



Photo 34. Large Carpet Roll on Pallet for Autoclaving



Photo 36. Vertical Packaging Orientation After Autoclaving



Photo 37. Full Exposure Control Sample



Photo 39. Connecting Thermocouple Wires



Photo 41. Removing BI Test Pouches from BDR



Photo 38. Stringing Thermocouple Wires Along the Top of the Bins



Photo 40. Removing BI Test Pouches From Sofa



Photo 42. BI Test Pouches Packed for Shipment to Laboratory



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