THE ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM

U.S. Environmental Protection Agency

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ETV Joint Verification Statement

TECHNOLOGY TYPE:	**Formaldehyde Gas Generator**		
APPLICATION:	**BIOLOGICAL AGENT DECONTAMINATION**		
TECHNOLOGY NAME:	**CERTEK®, Inc. 1414RH Formaldehyde Generator/Neutralizer**		
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The U.S. Environmental Protection Agency (EPA) has established the Environmental Technology Verification (ETV) Program to facilitate the deployment of innovative or improved environmental technologies through performance verification and dissemination of information. The goal of the ETV Program is to further environmental protection by accelerating the acceptance and use of improved and cost-effective technologies. ETV seeks to achieve this goal by providing high-quality, peer-reviewed data on technology performance to those involved in the design, distribution, financing, permitting, purchase, and use of environmental technologies. Information and ETV documents are available at www.epa.gov/etv.

ETV works in partnership with recognized standards and testing organizations; with stakeholder groups that consist of buyers, vendor organizations, and permitters; and with the full participation of individual technology developers. The program evaluates the performance of innovative technologies by developing test plans that are responsive to the needs of stakeholders, conducting field or laboratory tests (as appropriate), collecting and analyzing data, and preparing peer-reviewed reports. All evaluations are conducted in accordance with rigorous quality assurance (QA) protocols to ensure that data of known and adequate quality are generated and that the results are defensible.

The Building Decontamination Technology (BDT) Center, under ETV, is operated by Battelle in cooperation with EPA's Office of Research and Development. The BDT Center has recently (testing took place between November 2003 and April 2004) evaluated the performance of formaldehyde gas technologies for decontaminating indoor surfaces contaminated with biological agents. This verification statement provides a summary of the test results for the CERTEK®, Inc. 1414RH formaldehyde generator/neutralizer (1414RH unit).

VERIFICATION TEST DESCRIPTION

The 1414RH unit was verified in terms of its ability to reduce the amount of biological agent or surrogate on representative indoor surfaces. Qualitative factors also were evaluated, including ease of use and physical degradation of the indoor materials used as test materials.

The verification test consisted of using the 1414RH unit to decontaminate seven types of surfaces contaminated with biological agent (or surrogate) spores. The surfaces included industrial-grade carpet, bare wood (pine), glass, decorative laminate, galvanized metal ductwork, painted wallboard paper, and painted concrete. The condition of test surfaces was determined by visual examination.

Test surfaces, approximately 0.75 inch (in) x 3 in [1.9 centimeters (cm) x 7.5 cm], were wiped with 70% isopropanol and subsequently contaminated at challenge levels of approximately 1×10^8 viable spores per coupon. Spore suspensions were enumerated each day of use to confirm application density. Efficacy was evaluated using spores from *Bacillus anthracis* Ames strain, as well as the surrogates, *Bacillus subtilis* (ATCC 19659) and *Geobacillus stearothermophilus* (ATCC 12980). In addition, surrogate biological indicators (*Bacillus subtilis* and *Geobacillus stearothermophilus*) and biological spore strips (*Bacillus atrophaeus*) were used to further evaluate decontamination efficacy.

The 1414RH unit was operated using cycle parameters specified by the vendor to introduce the formaldehyde into a test chamber. The specified cycle parameters were as follows:

- Temperature: 16-32°C
- Relative humidity: 50-90%
- Paraformaldehyde: 0.3 grams/ft.^{3} of decontamination volume
- Contact time: 10 hours
- Neutralizer: ammonium carbonate
- Neutralizing time: 1 hour

The test chamber consisted of a Plas-Labs Compact Glove Box. The humidification capability of the 1414RH unit was not utilized; vendor-specified humidity levels were achieved with a nebulizer system incorporated into the test chamber. Humidity levels were monitored by a hygrometer positioned inside the chamber. The 1414RH unit lacks the capability to monitor formaldehyde concentrations inside the test chamber; however, this was achieved in real time using a spectrofluorometric technique. Subsequent to the treatment, the samples were visually examined for surface damage. Spores were extracted from the surfaces and, after appropriate serial dilutions, plated onto tryptic soy agar and incubated at appropriate growth conditions. Colonies were enumerated the following day. Efficacy of the decontamination procedure was evaluated by comparing the number of viable spores after decontamination to the number of viable spores from a control surface (of the same material, size, and challenge) that was not subjected to the decontamination. Efficacy was expressed in terms of a log reduction.

The extraction procedure did not remove 100% of the spores on the surface due to material-dependent characteristics, such as texture and/or porosity. To determine whether viable organisms remained on the test surface, the test coupon was placed in a liquid tryptic soy broth culture medium. The broth was checked after one and seven days for cloudiness, which indicated growth of residual viable organisms on the coupon. Growth may have resulted from the microorganisms in the sample not killed by the 70% isopropanol wipe or by the subsequent formaldehyde treatment.

QA oversight of verification testing was provided by the Battelle Quality Assurance Unit. Battelle performed a technical systems audit. A Battelle QA officer conducted a data quality audit (minimum 10%) of the test data. This verification statement, the full report on which it is based, and the test/QA plan for this verification are all available at www.epa.gov/etv/centers/center9.html.

TECHNOLOGY DESCRIPTION

The following description of the 1414RH unit is based on information provided by the vendor. This technology description was not verified in this test.

The 1414RH unit is designed to generate 50 to 90% relative humidity followed by formaldehyde gas generation for an operator-selected contact time. After the contact period, a neutralizer (ammonium carbonate) is automatically introduced into the decontaminated space. A white powder (hexamethylenetetramine) is produced in the 1-hour neutralization process. The 1414RH unit has a capacity of 240 grams of paraformaldehyde per canister, nominally sufficient to decontaminate *Bacillus anthracis* from an enclosure volume of 800 cubic feet (23 cubic meters). The 1414RH unit can be modified to decontaminate up to an enclosure size of 1,600 cubic feet (45 cubic meters).

The 1414RH unit weighs 55 pounds (25 kilograms), and is 12 in (30 cm) wide by 20 in (51 cm) in depth by 12 in (30 cm) in height. It operates from normal domestic power supply.

VERIFICATION RESULTS

By following the user manual, the 1414RH unit could be set up and ready for operation on the specially modified glove box within minutes. The 1414RH unit does not measure parameters such as relative humidity and formaldehyde concentration. The only maintenance required for the 1414RH unit during this verification test was the addition of paraformaldehyde and ammonium carbonate neutralizer at the beginning of each run. The automation of the 1414RH unit left little room for operator error.

Subsequent to decontamination, the test coupons were evaluated qualitatively for visible surface damage. No damage (e.g., change in surface texture, color) to any of the test materials was observed.

For biological agents and surrogates, a quantitative analysis of efficacy was performed by comparing the number of spores extracted from a control coupon to the number of spores from the decontaminated test coupons. Because of the magnitudes of difference, efficacy is reported as the log of the ratio of control to decontaminated samples. Thus, a 1,000-fold reduction in spores after treatment is reported as 3 (the log of 1,000). Quantitative performance results for efficacy, based on extraction of spores in triplicate from the test materials, are summarized in Table 1. Note that in Table 1 several values are listed as "≥;" for example, in the case of PW, the efficacy value is ≥5.17 for *B. anthracis*. For this PW efficacy value, no viable spores were detected following decontamination. This suggests that the calculated log reduction may not accurately reflect the decontamination process, but may be a result of the low recovery rate of 0.16%.

Table 1. Mean Efficacy for Spores

Material[a]		*B. anthracis*[b]	*B. subtilis*[b]	*G. stearothermophilus*[b]
Porous	**Industrial-Grade Carpet (IC)**	≥7.00 (7.00)[c]	≥8.04 (8.04)[c]	5.68 (4.81-7.18)[c, d]
	Painted Concrete (PC)	7.15 (5.93-7.76)[c]	6.02 (5.61-6.22)[c]	6.20 (4.03-7.29)[c]
	Bare Wood (BWD)	≥7.61 (7.61)[c]	6.58 (5.57-7.08)[c]	≥6.82 (6.82)[c]
Non-porous	**Glass (GS)**	≥7.71 (7.71)[c]	≥7.79 (7.79)[c]	≥7.24 (7.24)[c]
	Decorative Laminate (DL)	6.47 (5.61-7.66)[c]	7.29 (6.38-7.74)[c]	≥7.12 (7.12)[c]
	Painted Wallboard Paper (PW)	≥5.17 (5.17)[c]	≥7.68 (7.68)[c, d]	≥7.19 (7.19)[c, d]
	Galvanized Metal Ductwork (GM)	≥7.86 (7.86)[c]	6.24 (5.39-7.87)[c, d]	≥7.64 (7.64)[c]

[a] Three replicates were used for each test material for each organism.
[b] Mean log reduction in spores with range in parentheses.
[c] Mean significantly different from 0 (P 0.05).
[d] Surrogate significantly different from *B. anthracis* for specified material (P 0.05).

After extracting the spores from the samples, the coupons were incubated in tryptic soy broth as an additional qualitative evaluation of efficacy. The results from the qualitative analysis of residual test spores or other surviving microorganisms following decontamination are summarized in Table 2.

Table 2. Growth (After Seven Days) of Residual Organisms on the Materials

Material[a]		*B. anthracis*[c]	*B. subtilis*[c]	*G. stearothermophilus*[c]
Porous	**Industrial-Grade Carpet[b] (IC)**	0	0	0
	Painted Concrete (PC)	0	0	+
	Bare Wood (BWD)	0	+	0
Non-Porous	**Glass (GS)**	0	0	0
	Decorative Laminate (DL)	0	+	0
	Painted Wallboard Paper (PW)	+	+	0
	Galvanized Metal Ductwork (GM)	0	0	0

[a] Three replicates were used for each test material for each organism.
[b] The carpet, as manufactured, contains a broad-spectrum antimicrobial chemical. Although no bacterial growth was observed for these samples, no conclusions can be drawn as to residual organisms on the carpet.
[c] 0 indicates no growth in media for any of the samples after 7 days. + indicates growth in media for one of the three samples.

Surrogate indicators (*Bacillus subtilis* and *Geobacillus stearothermophilus*) and biological spore strips (*Bacillus atrophaeus*) were exposed to the formaldehyde treatment concurrently with decontamination of the test coupons described above. Some surrogate biological indicators (*Bacillus subtilis* and *Geobacillus stearothermophilus*) and biological spore strips (*Bacillus atrophaeus*) exhibited growth after decontamination (Table 3). These qualitative results suggest that in ≥ 50% of the cases, decontamination effectively killed all viable surrogate spores.

Table 3. Post-Decontamination Growth of Surrogate Indicators and Spore Strips

Biological Indicators/ Spore Strips[a]	Growth[b]	
	Day 1	**Day 7**
Biological Indicator (***B. subtilis***) (n=13)	7.7%	23.1%
Biological Indicator (***G. stearothermophilus***) (n=12)	16.7%	50.0%
Spore Strip (***B. atrophaeus***) (n=19)	0.0%	26.3%

[a] For each testing day, 2 to 3 replicates of two or three types of the biological indicators and spore strips were included.
[b] Reports percentage of the biological indicators or spore strips exhibiting growth in media after 1 or 7 days.

In summary, the 1414RH unit did not change or damage any of the materials evaluated in the test. ETV testing of the 1414RH unit provided a range of results, depending on the material being decontaminated. The 1414RH unit demonstrated a log reduction for *B. anthracis* spores ranging from 5.17 on painted wallboard paper to 7.86 from galvanized metal ductwork. Significant differences in efficacy between *B. anthracis* and both surrogate organisms were observed for various materials. Results for the surrogate biological indicators (*B. subtilis* and *G. stearothermophilus*) and biological spore strips (*B. atrophaeus*) suggest that in most cases the 1414RH unit was effective in inactivating spores.

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