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Dankert, John, R, Ph.D.
Director Research and Development

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SteriFx, Inc.
1868 Kings Hwy., STE 120
Shreveport, LA 71103

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14. ABSTRACT

SteriFx, Inc has demonstrated feasibility that our technology can provide an answer to the problem of biological decontamination based upon the properties of our new aqueous compound, CleanseFx. This proprietary compound is the basis for the development and commercialization of a line of antimicrobial and wound care products, even to include a cold sterilant. The compound is an aqueous acidic mixture with a pH of less than 1, normally considered toxic or dangerous, however the method of manufacture and final composition of the compound results in a solution that is acidic while retaining a large margin of safety. The low pH of the solution provides for an environment that destroys bacteria on living skin within minutes, without harming the host. This efficacy coupled with safety could provide a system for personnel and civilian decon. A military training mission demonstrating use was carried out, and indications are that CleanseFx was preferred over standard hypochlorite solutions that harm skin, eyes, clothes, as the hypochlorite label specifically prohibits use on human tissues. CleanseFx is currently marketed as an FDA-cosmetic product.

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a. REPORT	b. ABSTRACT	c. THIS PAGE			Dr. John R. Dankert
U	U	U	SAR	23	19b. TELEPHONE NUMBER *(Include area code)* (318) 425-2515

"Novel Concepts for Soldier-Centric Technology in Non-Traditional Combat Casualty Care"

"Development of a Decontamination System for BW Agents for Military and Civilian Use: Decon of Soldier Wounds, Personnel, and Materiel"

April 11, 2003

Sponsored by

Defense Advanced Research Projects Agency (DOD)
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Contract No. DAAH01-02-C-R173 – ADDENDUM

SteriFx, Inc
1868 Kings Highway
Shreveport, LA 71103
Phone Number: (318) 425-2515
jdankert@sterifx.com
www.sterifx.com

Principal Investigator,
John R. Dankert, Ph.D.

Effective Dates: Nov 19 2002 – May 19 2003

"Development of a Decontamination System for BW Agents for Military and Civilian Use: Decon of Soldier Wounds, Personnel, and Materiel"

Contract Expiration Date: May 19, 2003 Reporting Period: **FINAL REPORT**

Introduction:

SteriFx, Inc has developed a platform technology based upon the unique combination of providing an aqueous solution with a low pH (<1) that is not harmful to human tissues. The base components are on the GRAS list, can be ingested, and disposal is environmentally friendly. This combination is the basis of Fx technology: the ability to expose pathogens, toxins, and chemical agents to such extreme pH levels permits inhibition, inactivation, and destruction of noxious agents. Importantly, it is difficult to misuse Fx technology due to the harmlessness of the formulations, even to be used on contaminated wounds and personnel directly. Fx technology has one formulation that is sporicidal, killing *Bacillus* spores within minutes. Another destroys (>99.9999%) vegetative bacteria such as *E. coli* and *Staph* within seconds without any requirement for power or elevated temperatures. The low pH denatures biological toxins such as botulinum, and can inhibit CW mimes. SteriFx, Inc is in the process of establishing one formulation as a cold sterilant. For a decon system for military and homeland defense, this would provide a broad-spectrum anti-CBW system that is difficult to misuse, requires no special training, power, or equipment, and does not require time-consuming prior identification of the agent to be effective.

Measures to protect civilians, emergency first responders, and military personnel from biological warfare (BW) agents presents a major task for governmental authorities. The decontamination of BW agents on equipment, buildings, vehicles, and even casualties and contaminated wounds is included in the task for minimal amounts of threat agent. The current environment of bioterror fear and the ever-present risk posed from BW agent development in rogue nations has made civilian authorities much more concerned with possible scenarios that result in the devastation or elimination of emergency personnel and primary medical treatment centers, and the spread of the agent through civilian to civilian contact.

Methods to prevent contamination for those at risk at present rely on protective suits and closed breathing units, not at all practical for civilians in an emergency situation. Even evacuated casualties removed to treatment sites by protected transport personnel present a threat to un-suited medical personnel. The time required to deploy protective clothing even if enough were available preclude this option, and does not decontaminate the suspected BW agent. The panic resulting from an incident would be uncontrolled for the most part, and methods to decontaminate individuals are not in place.

The use of physical methods such as heat and irradiation cannot be used for these applications, however chemical methods to decontaminate threat agents are possible. At present, the U.S. Army Medical Research Institute of Infectious Diseases (in the 4th edition of the Medical Management of Biological Casualties Handbook published in February 2001) recommends that chemical disinfectants, even chlorine tablets used in pools dissolved in water, can be used. The Handbook warns that like chlorine at high concentrations, most are harmful to human tissues, clothing, equipment, etc. This would prohibit the use for civilian applications to decontaminate. Many are also expensive, difficult to apply, and pose special training and disposal considerations themselves, others are explosive or difficult to store, and/or require large power sources.

SteriFx, Inc believes that a liquid spray, either delivered by water spray or fogger, that could inactivate a broad spectrum of BW agents could address this problem. It is also vital that it is not harmful nor appears to be "out of the ordinary" in terms of texture, taste, or smell to limit population apprehension and further panic. The result would be that treated individuals would

become wet, however they could continue evacuating without loss of senses (whereas a foam would block vision, etc). It is likely that the individuals would believe that the application was water, and therefore be more at ease. For emergency first responders, this would not preclude them from attending other duties. If no obstruction of vision or emergency personnel uniforms are obscured, and personnel can continue emergency procedures, and would provide the responders a means to maintain "**Persistence in Crisis (PIC)**" for the event.

Hypothesis:

SteriFx, Inc can provide an answer to the problem based upon the properties of our new aqueous compound. This proprietary compound is the basis for the development and commercialization of a line of antimicrobial and wound care products, even to include a cold sterilant. The compound is an aqueous acidic mixture with a pH of less than 1. This pH is normally considered toxic or dangerous, however the method of manufacture and final composition of the compound results in a solution that is acidic while retaining a large margin of safety. The low pH of the solution is thought to provide for an environment that destroys bacterial, viral, and fungal pathogens through the denaturation of multiple components of the pathogen, and therefore it has a broad spectrum of activity. Resistance to our compound therefore cannot be developed. Although the mechanism by which the compound remains safe for use on skin is unknown, we are currently obtaining toxicological data for one composition of the compound to independently establish safety for purposes of label warnings and proper disposal.

The basis for this project results from our preliminary study of the ability of the compound to kill pathogens, detoxify biological agents, and to inactivate chemical threat agents. The solution is aqueous and can therefore be applied in many forms and can be easily packaged with sponges or bandaging. During the course of this work and in working with the compound for other applications, we have obtained anecdotal evidence that the compound can also be used to accelerate the healing process. In some of our preliminary work, we had sought to detoxify threat agents in wounds, and also to inhibit infection of open wounds through the topical application of the compound. This has led to our preliminary findings that the solution can accelerate the healing of animal wounds as well as sunburns, insect bites, and lesions caused by athlete's foot fungus in humans. A study to measure the ability of one form of the compound to accelerate wound healing in an equine model was begun in Dec 2001. For other military applications, it is our intent to develop a "reactive barrier" which will protect a soldier from BW agents.

A major objective for this project is to provide for the commercialization of the Decontamination Compound for Military and Civilian use. SteriFx personnel have experience in commercializing products based upon the technology. This will enable us to move more quickly through the regulatory processes to market the compound. The investment required for the higher level regulatory clearances can be more readily attained if the company has completed the studies and objectives of this project, and has a successful track record and a revenue stream from other products based upon the technology. Finally, the infrastructure to produce the compound will be effectively in place.

TECHNICAL OBJECTIVES:

The main objective of this project is to demonstrate the feasibility of the novel solution to function as a **Threat Agent Decontamination Compound** and/or **Reactive Barrier**. The ultimate goal is to provide a system for the soldier in the field, in military decon units, and in civilian emergency units and possibly firefighters to prevent the spread of BW agents and to prevent exposure to the agents. Achieving this goal will require governmental approvals for use of the product on humans through clinical trials and experimental evidence. This costly and time-consuming process will be required in later Phases of the project. In Phase I we seek to **demonstrate feasibility that the compound functions as a decontaminating compound** for biological agents on inanimate surfaces, skin, and wounds.

Summary of Milestones:

1) **Demonstrate reduction of pathogens greater than effectiveness of positive control.**
    a. Task 1- Establish feasibility of CleanseFx to reduce bacterial loads in contaminated wounds.
    b. Task 2- Determine effect of CleanseFx on animal model tissues.

2) **Measure the effect of Fx Technology on common metals and other substances.**
    a. Task 1- Measure weight loss of sample metals incubated in Fx Technology
    b. Task 2- Determine any detrimental effects of Fx Technology on plastics, rubber and plastic tubing, and clothing.

3) **Demonstrate ability of CleanseFx to function as skin cleanser in military setting.**
    a. Task 1- Provide Military Field Users with CleanseFx for evaluation.
    b. Obtain guidance from users on benefits of CleanseFx in practice.

4) **Deliver a Final Report on the Success/Failures of CleanseFx Technology delineating improvement in terms of relative effectiveness.**

Results:

Demonstrate reduction of pathogens on living tissue.

This task has been initiated in a pilot project to study the ability of SteriFx Technology to accelerate wound healing in the porcine model at University of Miami, Department of Dermatology. Preliminary results were that the sensitivity of the Yorkshire Pig to SteriFx Technology will preclude further use of this model for future studies on pathogen reduction. We have reviewed other models to use for pathogen reduction assays, and have used a mouse skin model for this portion of the project.

A mouse model was used to demonstrate the efficacy of the SteriFx technology (in the form of the product, "CleanseFx") to kill pathogens on living tissues. This would be the first step towards developing a compound that could function as a decontaminating agent for biological agents for both unbroken skin and for decontamination of wounds.

Standard laboratory white mice, germ-free, had a portion of hair removed (shaved) off the back and flanks, and were inoculated with live cultures (early-log phase) of *Staphylococcus epidermidis* (approximately 10^5 bacteria per patch) by atomization. Inoculated bacteria were allowed to air dry, and swabs were taken for the "Before" counts. Skin was then treated with water (0x) or 0.5x CleanseFx (0.5x CleanseFx was prepared by mixing equal volumes of CleanseFx and distilled water, producing a "half-strength" solution). After 15 min, swabs were taken for the "After" counts. Sterile swabs were saturated with sterile saline, suspended in 1.0ml of the saline to dislodge bacteria from the cotton swab, and diluted/plated for bacterial enumeration. Cell densities were calculated from counts of *Staphylococcus epidermidis* recovered on Baird-Parker Agar (TSA basal layer) plates following triplicate platings and 24 h incubation. The results are presented below in Figure 1.

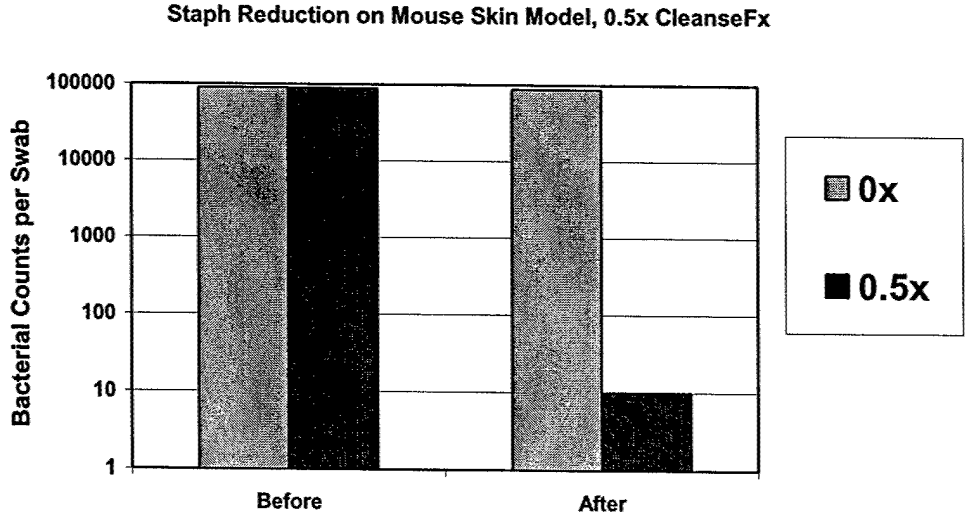


Figure 1. Comparison of the reduction in bacterial counts recovered from skin swabs of inoculated skin patches by water treatment (blue) or by 0.5x Cleanse Fx.

Another experiment was performed using water as a control, plus three different concentrations of CleanseFx (0.1x, 0.5x, and 1.0x, prepared by mixing with the appropriate volume of distilled water. Inoculation of mice with bacteria, swabs, treatments with water or various concentrations of CleanseFx, plus enumeration of viable bacteria were performed as in Figure 1. The results are presented in Figure 2 below.

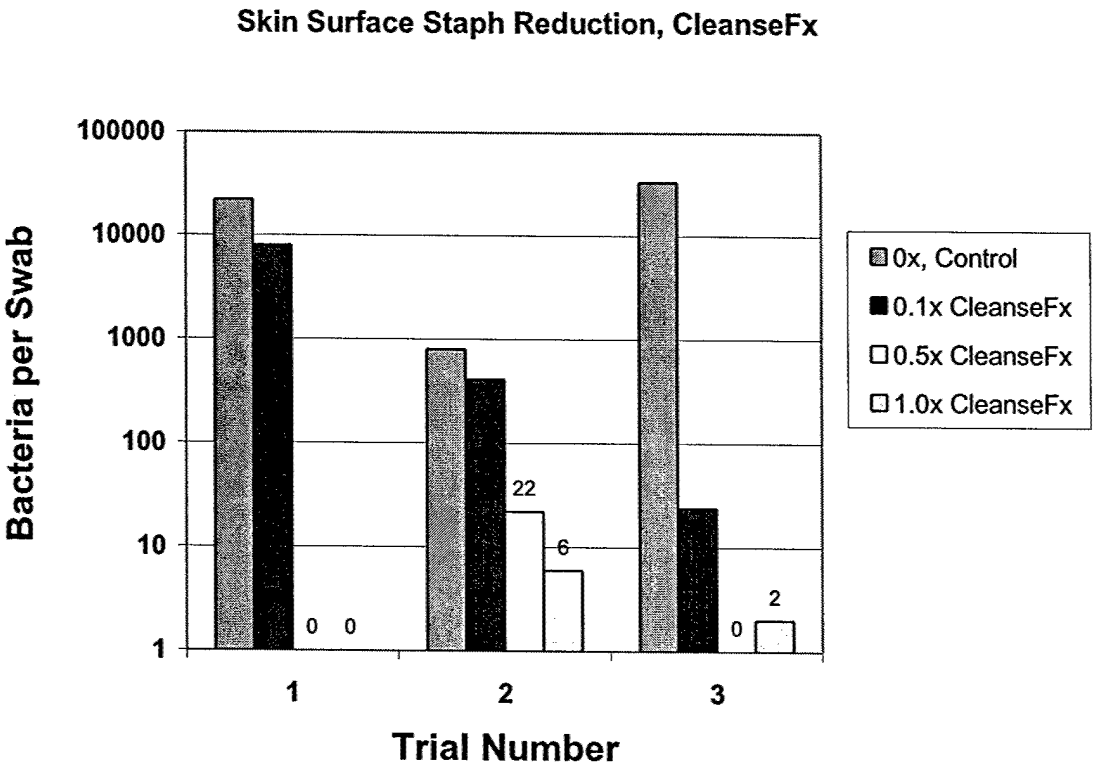
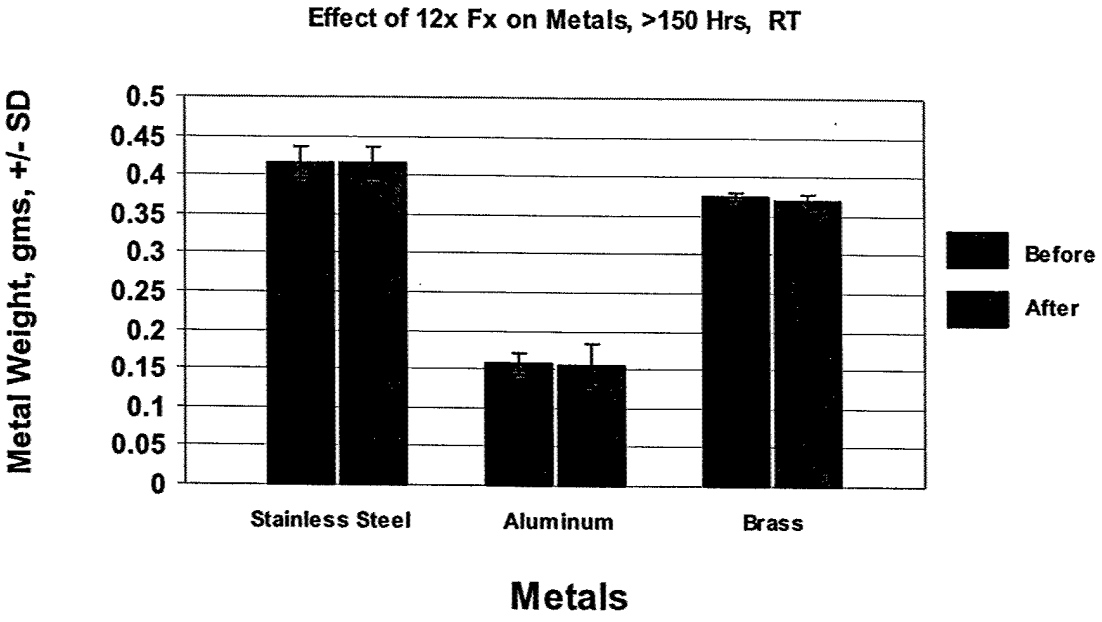


Figure 2. Demonstration of bacterial reduction using a live skin model as a function of concentration of CleanseFx.

The above results of Figures 1 and 2 demonstrate the bactericidal effect of CleanseFx using a live skin model system, and a standard bacterial target, *Staphylococcus epidermidis*. Compared to the control, the CleanseFx solutions, even at a 10-fold dilution of the normal product concentration showed significant bactericidal activity. It should be noted that the safety testing of the product was performed using the "Full-Strength", or 1.0x, product. Lower concentrations should be even safer, while providing for 3 to 5 logs reduction in bacterial loads. These concentrations of pre-inoculated bacteria represent a massive load relative to what would be expected from a biological agent attack, and provide evidence that CleanseFx can function as a skin cleanser with the added benefit of demonstrable reduction in bacterial counts from the surface of the skin.

Measure the effect of Fx Technology on common metals and other substances.

Incubating various metals in high concentrations of CleanseFx for long periods of time, and comparing the weight of the metal before and after treatment have addressed the effect of SteriFx Technology on metals.



As can be seen, prolonged incubation (about a week) at 12x concentration of Fx resulted in no significant differences in weight. However, for zinc (not shown) we saw an immediate oxidation reaction that would indicate unsuitability for CleanseFx-zinc interactions. However, it should be noted that **these concentrations represent those to be used for shipping of concentrated solutions of CleanseFx only**. It was our intention to address these issues for concerns from spillages of the concentrate. SteriFx has obtained preliminary skin-testing toxicity on the 12x concentrate of CleanseFx (performed by SGS US Testing), where a 10-minute exposure to the concentrate did not harm skin using a guinea pig model (*not shown, available on request*). There is no concern for the 1x concentration or lower solutions, tested in the formal EPA toxic six-pack battery of tests (described in our application for this funding).

Additional Information: Inactivation of Chemical Threat Agents in Wounds.

Previous work includes the completion (28 JAN 98) of contract number: DAMD17-97-C-7031 funded by the U.S. Army Medical Research and Materiel Command (POC Ms. Betty Nelson (301)-619-7328). This project, entitled: "Development of a Decontamination Compound for Therapeutic use on Chemical Threat Agent Wounds" involved the demonstration that Fx Technology could inhibit the activity of the CW agent mime, paraoxon.

Demonstrate ability of CleanseFx to function as skin cleanser in military setting.

Introduction:

The individual warrior already carries an extremely large amount of equipment into combat already, and therefore, CleanseFx could take the place of several items based upon the the antimicrobial properties of the technology. Namely:

- The M291 Decon Kit (Chemical Biological Warfare)
- The Isopropyl alcohol swabs of the medical assemblage
- The Iodine Tablets for the treatment of water
- The baby wipes for personal hygiene frequently found in combat

To attain this goal, CleanseFx must prove to be a suitable replacement for such items. We decided to approach this in a two-pronged attack. This was to demonstrate that CleanseFx is superior to current equipment in both 1) technical testing as well as 2) user testing. Technical Testing addresses CleanseFx performance in the laboratory as described above for the results of bacterial reduction on a living skin model, and User Testing addresses CleanseFx performance with the warrior, addressed in this portion of the final report.

The effort to provide our technology to function as a cleanser for a military setting has required the manufacture and delivery of the technology to military users as a first step. This has been accomplished and delivery occurred (100 55-gallon drums of CleanseFx, 1x concentration, ready-to-use) on 16 December 2002 to GTMO Expediter at Blount Island Marine Terminal in Jacksonville, FL.

The next step was to provide training and direct user testing. The goal was to convince the warrior that CleanseFx is the state-of-the-art decontamination fluid for use on the victims of a Chemical Biological Warfare Attack. The tactic was User Testing.

User Testing was addressed by teaming with the Preventive Medicine Department of the Naval Hospital Guantanamo Bay, Cuba. They agreed to host Patient Decontamination Training 11-15 February 2003. In this training, CleanseFx would be used as the decontamination fluid.

Mr. Rob Colbert was retained to represent SteriFx. He was chosen due to his experience in the Fire Department, as well as the U.S. Army. His most applicable experience was the fact that he had just returned from Afghanistan where he served as a Warrior Medic with the U.S. Army's 101st Airborne Division (Air Assault). His primary duty was field hygiene and personnel decontamination in Kandahar. This was the most recent combat experience anyone could have since it could be measured in weeks.

To ensure that the training was successful, a pre-deployment training was conducted at Frederick, Maryland 31 JAN 03 to 02 FEB 03. It was called Winter Harvest I (WHI). A dress rehearsal was done with CleanseFx as the decontamination fluid in a Fire Department Hazardous Materials scenario. A second, military scenario was done with gas mask and decontaminable litter. The training was documented and very few problems were encountered.

Mr. Colbert deployed to Guantanamo Bay, Cuba. This full-blown operation was called Winter Harvest II (WHII). Four training sessions were performed over a two-day period. Both civilian and military scenarios were run (Level B suits as well as MOPP gear). 46 personnel were

trained. They represented the U.S. Army, U.S. Navy, and the Federal Fire Department. The training was so successful that several of the students demanded to be given samples to be stored in their workspaces.

A review of any of the versions of Department of Defense Instruction 5000 show that for successful transition of a product, the Combat Developer (CBTDEV), Material Developer (MATDEV), and Logistician (LOG) must be brought into an Research & Development program as early as possible. SteriFx went about identify this group of people for all four services.

Results:

Department of Defense, Personnel & Patient Decontamination Training
Guantanamo Bay, Cuba
11 – 15 FEB 03

The Industrial Health Preventive Medicine Department of Naval Hospital, Guantanamo Bay, Cuba sponsored a Product Investigation of CleanseFx as an alternative decontamination fluid. It was decided that the best way to perform the Product Investigation was to hold Personnel and Patient Decontamination Training 11 – 15 February. Feedback from Operational Personnel was solicited.

This Product Investigation will provide decision-makers with information on a potential alternative to status quo. But in the broader sense, this investigation will provide data to the Department of Defense on a product that has other potential uses. An additional purpose of the training was to familiarize Army and Navy personnel as well as Civilian Fire Fighters with CleanseFx skin cleanser as a decontamination solution, and to inspire customer confidence in the product.

Currently, guidance derived from NBC warfare doctrine dictates that military personnel dilute hazardous calcium hypochlorite into a 0.5% chlorine solution. This solution degrades rapidly when exposed to ultraviolet light. It must be used quickly due the chemical instability. In other words, it has a short shelf life. It is corrosive to metals such as stainless steel and aluminum and bleaches and discolors items.

CleanseFx™ Skin Cleanser is made by SteriFX Inc., and has already been tested in the laboratory. It has a patented formula approved under the Federal Food Drug and Cosmetic Act (FSC-8510, SIC-2844, NAICS-325620, 325998) as a skin cleanser. Ingredients are listed as water, hydrochloric acid, citric acid, and phosphoric acid. SteriFx makes no therapeutic claims of affecting the structure or function of the body. Therefore, no regulatory clearances are required from the Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) for that purpose.

CleanseFx has proven to be effective against the following microorganisms: Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Salmonella spp., Bacillus subtilis both vegetative and spore forms, Enterobacter aerogenes, and Clostridium sporogenes. It has passed the Industry Standard Benchmark for toxicity. It is non-toxic for: Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation Toxicity, Acute Eye Irritation, and Skin Sensitization.

Although it is not cleared for the *treatment* of wounds, preliminary data show that it can destroy contaminating pathogens, and in a previous DARPA-funded project, demonstrated the ability to

accelerate wound closure in an equine laceration model (*final report available upon request*). The low pH of the technology could provide for the enhanced release of oxygen from oxyhemoglobin. This oxygen will be used by damaged tissues, generate chemotactic factors that attract antibacterial and repair systems to the site of damage, and also augment the natural bactericidal activity of phagocytic cells of the immune system. All of this promotes wound healing, and also has shown to minimize scarring in an equine model.

This skin cleanser claims to help remove organic and inorganic debris from the surface of the skin. Due to the low pH of the solution, the pathogens present in the area will be adversely affected by this acidic milieu. The low pH of the environment is known to inhibit the action of many bacterial toxins, such as botulinum, and low pH is commonly used to treat/counter-act many venomous stings and bites. Laboratory Test results for CleanseFx were given to the Industrial Health/Preventive Medicine Department, Naval Hospital, Guantanamo Bay, Cuba.

Technical Details of Decontamination

Current guidance on initial decontamination of patients prior to their entry into the military hospital is derived from guidance on patient decontamination in an NBC Warfare military environment (specifically Marine Corps Warfighting Publication (MCWP) 3-37.3). These policies and procedures met the requirement. However, experience in implementation led to the realization that these procedures needed to be tailored to the mission. To discuss the possible incorporation of this COTS item into decontamination procedures, it is important that we have a review at the basic level.

The decontamination team is comprised of four elements: decontamination, medical, security, and service support. The decontamination element decontaminates patients. The medical element is capable of providing triage support to casualties during and after decontamination. The security element provides security for the site as well as assets operating within the area. The service support element provides shelter, food and water so the team can operate at the site.

The decontamination element consists of Marines and Sailors. The decontamination element establishes itself near the medical element's triage station. There, personnel and casualties, whether ambulatory or non-ambulatory, are processed through a series of stations derived from Nuclear, Biological and Chemical (NBC) decontamination standards. As contaminated individuals enter the area, their personal effects and equipment are collected, and clothing items are removed. The individuals are then sprayed and sponged with a .5 percent bleach solution, and led through a shower system to rinse off the decontaminating liquid. Personal effects and equipment are also processed through the cycle. Once casualties are decontaminated, element members will change bandages and dressings if needed, then transport the individual to waiting medical personnel.

The security element is a standing unit of infantrymen. They have a force trained in a variety of roles including security patrols, Military Operations in Urban Terrain, riot control and vehicle and personnel search. Members can be tasked with providing security patrols, quelling unrest, detaining hostile forces, assisting with the evacuation of casualties, securing the area a providing security to the site. The unit carries the wide range of small arms to includeM870 shotguns, M16-A2 service rifles, M-203 40mm grenade launchers M-249 Squad Automatic Weapons and M-204G medium machine guns.

The medical element consists of physicians, Environmental Health Officers, Physician's Assistant, nurses, and 17 corpsmen. The element is tasked with treating any chemical or biological casualties, including those suffering from nerve, blister or blood agents. The staff is capable of administering antibiotics and antidotes, as well as treating chemical burns and conventional injuries. Members of the medical element will go into an affected area to provide on-scene life-saving medical attention. There, they will stabilize and evacuate casualties to a predetermined decontamination area. At that point, the element will either evacuate the casualties to available local medical facilities or to their Shock/Trauma Platoon, which can provide 72-hour stabilization for the patients.

The service support element consists of military personnel. Its members provide all ground transportation on site, using both light and medium lift. They provide water, utilities and heavy equipment support at the site. The supply section provides supply and warehousing support to the team, ammunition support to the security element, and assists in fiscal/contractor support services within the area. The supply section includes a contracting specialist, who has the capability to procure logistical support from the local community near the site. The service support element is able to provide housekeeping support for the team as well as limited support to the site. In a deployed status, the service support element can self-sustain the team for 10 - 14 days, and arrange further logistical support to sustain operations.

Materials and Methods of Training

Equipment Check

Upon arrival, an inventory was done on the equipment available for the Training. Chief Faustino of the Naval Hospital Guantanamo Bay, Preventive Medicine Department unlocked the CONEX container that would be the staging area for the training. An inventory of the equipment revealed that all of the items shipped by SteriFx were present and accounted for. All equipment provided by the Naval Medical Logistics Command (NMLC) were present and accounted for as well.

The site provided equipment as well. The U.S. Army, represented by Lieutenant Dabbs, had provided Mission Oriented Protective Posture (MOPP) equipment. The Naval Hospital had provided a decontamination rinse shower as well as all of the hardware to marry it up to a fire hydrant. The Navy provided the gas masks as well.

CDR Thomas, Chief, Preventive Medicine Department gave a briefing on the Emergency Plan. This would be the plan followed in the event of an actual incident involving chemical or biological warfare agents. The plan was to be the basis for the Decontamination Training. It was CDR Thomas' desire to train as realistically as possible. Therefore the training was tailored to the Emergency Plan all the way down to the exact location of the decontamination station. A tour of the site followed. After the briefing, a representative of the Navy wanted to inspect the CleanseFX that had been shipped. This also provided the opportunity to draw off the amount of fluid to be used in the training.

Shipping, Storage and Handling Test

An NMLC Representative formally requested that the logistics of this exercise be documented. The following was taken from his request via electronic mail:

> *"Cargo placed in containers must be secured to withstand the most stringent transportation modes to which it will be subjected during multi-modal shipment. For example, containerized cargo/equipment can be moved through any one or any combination of highway, rail, and ocean modes. Therefore, it must be secured to withstand the most severe load conditions to which it will be exposed. Shippers must plan to have adequate blocking and bracing material on hand before loading the containers."*
>
> *"Container contents may be subjected to sudden jolts during transport. Containers loaded on rail cars must withstand the impact, up to 8 miles per hour, resulting from coupling the rail cars together in the rail yard. Twenty-foot containers picked-up with trucks will be tilted to approximately a 35 degree angle during the loading process. All containers are subject to varying G forces during transit."*

The NMLC Representative referred to the US Department of Transportation publication, *"A Shippers' Guide to Stowage of Cargo in Marine Containers."* And, he added, more guidance for securing dry cargo and vehicles in containers can be found in MTMCTEA Reference 96-55-23.

Evaluation Checklist

One hundred 55 gallon barrels, palletized four to a skid, were being stored at the bottom of the hill behind the Preventive Medicine Department. There was concern about the storage temperatures and how the fluid would be effected. Even in the middle of February, Guantanamo Bay, Cuba has an average daily temperature of 82°F. Mr. Roden of SteriFX was contacted to immediately address the concerns. Even though temperature was not a major factor, Navy personnel have decided to find covered storage space for it in the near future.

To comply with the NMLC request, barrels were visually inspected to see if the shipper did the following:

- Distributed the weight of the cargo evenly over the floor of the container.
- Blocked and braced the cargo to prevent movement in any direction.
- Ensured all supplies containing liquid are packaged in appropriate containers.
- Kept the center balance of the cargo as near as possible to the center of the container.
- Never exceeded the weight limitations of the container.
- Weighed containers before shipment at the origin and recorded the weight.
- Observed procedures for hazardous cargo

- Always stowed upright.
- Stowed drums with bungs uppermost if the bung or closure is at one end.
- Did not re-use single- or one-trip drums. Second-hand drums, unless thoroughly reconditioned and tested, may give trouble either because of dents at the chine or because of previous wear and tear at the closures.
- Used adequate seals on locking levers and sealing rings of open-end drums. Failure of seals may result in accidental opening of covers.
- Did not overload. Drummed cargo tends to be very dense. Ensured the weight of the cargo and dunnage does not exceed the container weight capacity and over-the-road limitations.

The NMLC worksheet is attached as Appendix A.

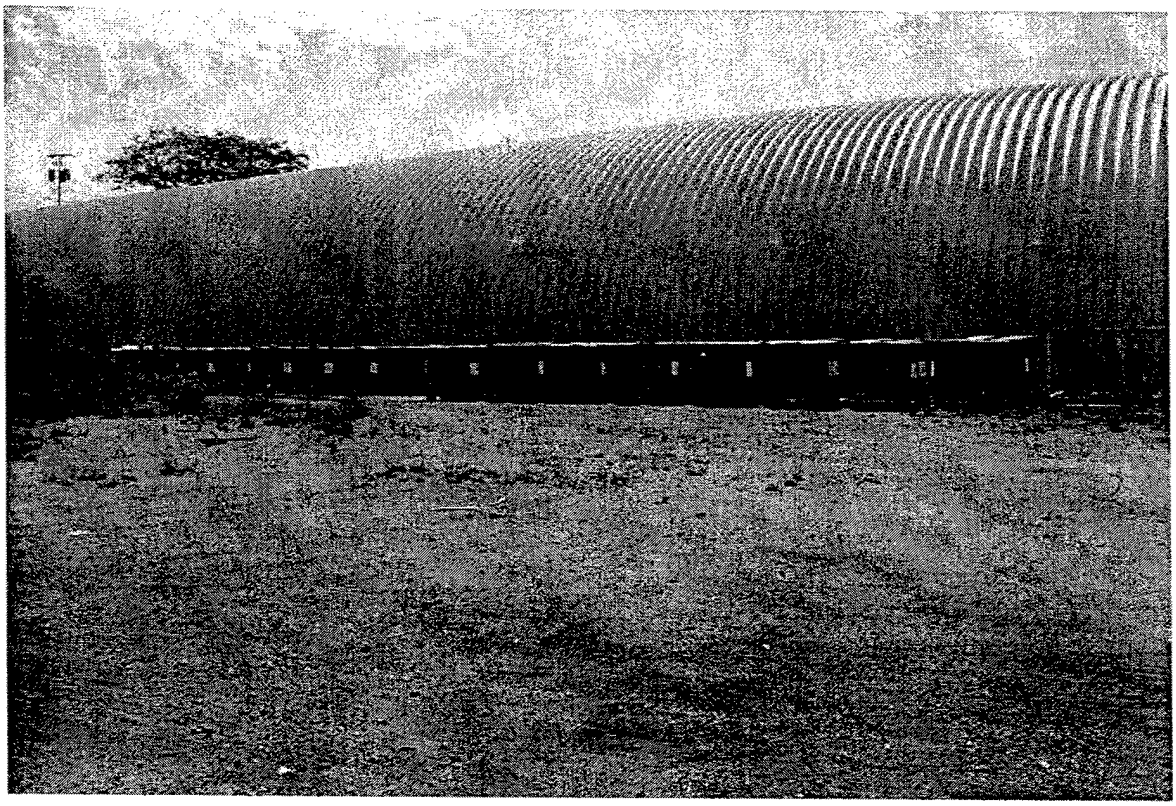


Figure 1. Storage of CleanseFx Decontamination Fluid

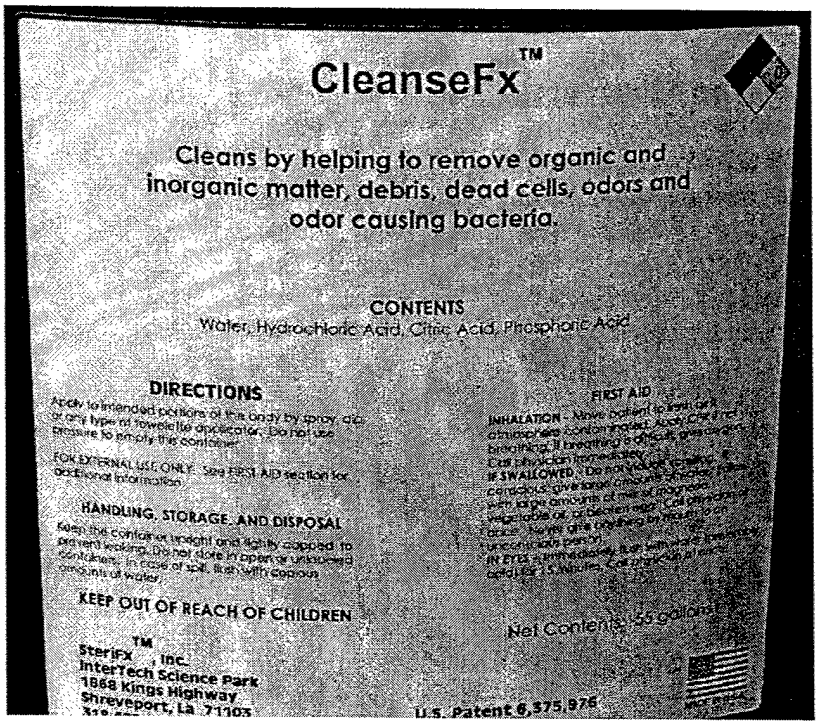


Figure 2. SteriFx Labeling

The Preventive Medicine Department attached the Material Safety Data Sheet (MSDS) to the barrels (see Figure 3.)

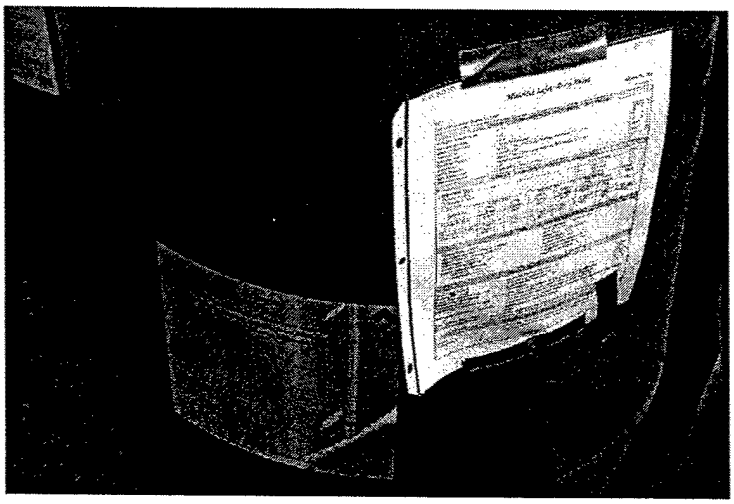


Figure 3. Material Safety Data Sheet on Barrel.

Two gallons was pumped out of one of the barrels. It would be used during the training evolution.

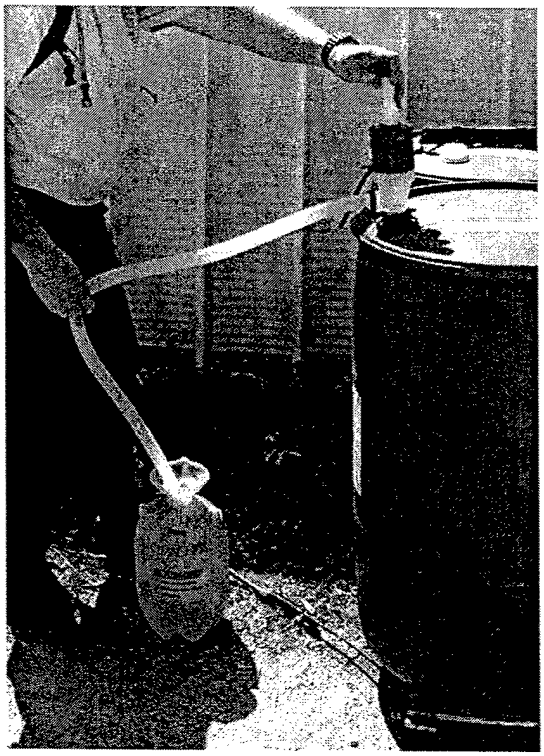


Figure 4. Two Gallons Being Removed for Training

Description of the Decontamination Process:

STEP 1: Clothing Removal

Figure 5. Clothing Removal

Equipment: Two plastic bags/containers and a ground sheet.

Action: Remove outer clothing and gloves and place in first container. Take care not to touch outer clothing. Step forward. Remove respirator. Remove inner clothing and place in second container

STEP 2: Decontamination

Figure 6. Decontamination

Equipment: Wading pool, garden sprayer, sponge, and bucket of rinse water.

Action: With the assistance of the decontamination personnel, wash body with decontamination solution, paying particular attention to the fingernails and hairy portions of the body.

STEP 3: Rinse

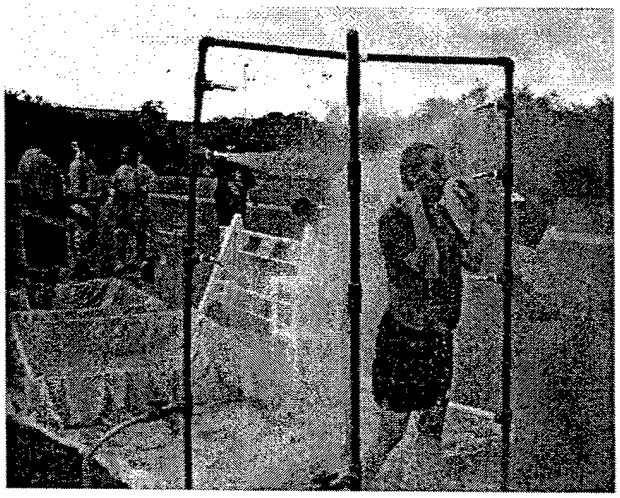


Figure 7. Decontamination Rinse Shower

Equipment: Rinse Shower, garden sprayer, bucket of rinse water, plastic stand, and towels.

Action: With the assistance of the decon personnel, rinse the body with clean rinse water. Dry and monitor for contamination. If the patient is believed to still be contaminated, repeat the washing and rinsing process. Rinse face and hands.

STEP 4: Redress

Equipment: Chair, disposable towels, and clean clothing.

Action: Redress in clothing provided.

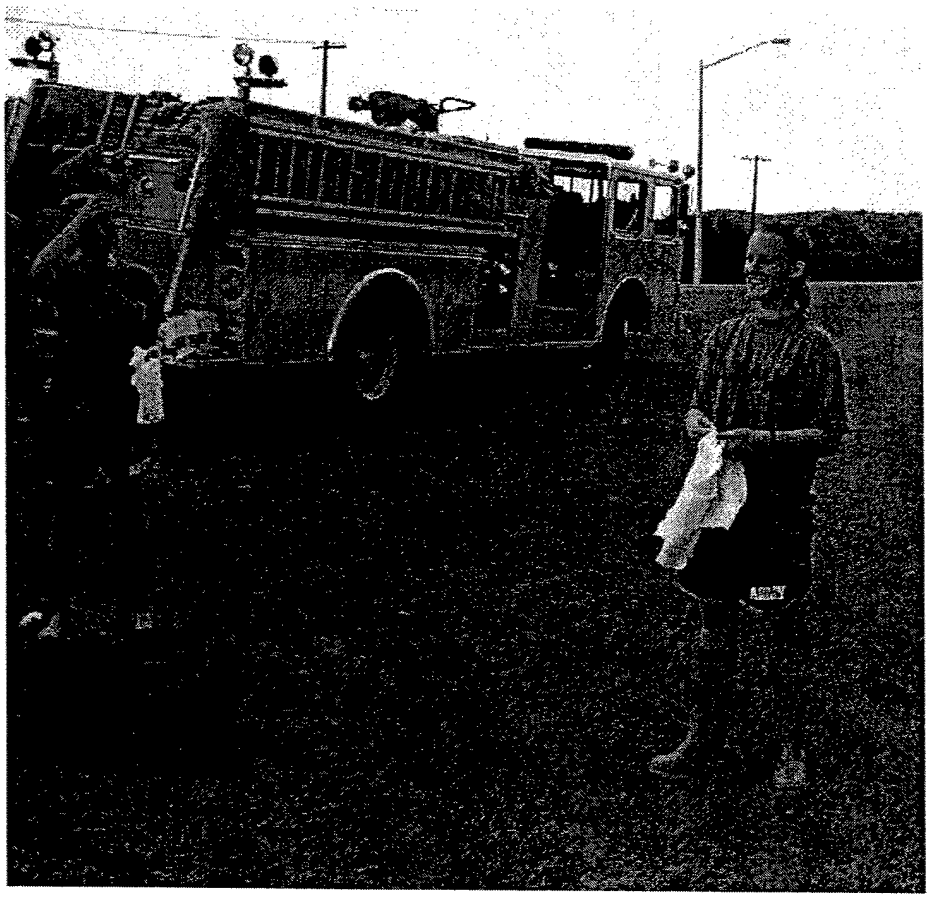


Figure 8. Redressing after Decontamination

Equipment

1.) Garden Sprayer (2)
2.) Roll of 4-6mm Polyethylene
3.) Wading Pools (2)

4.) Decontamination Rinse Shower with hardware for hydrant
5.) Plastic Trash Cans
6.) Plastic Trash Bags
7.) Trauma Shears
8.) Sponge, Large
9.) Duct Tape
10.) Plastic Bucket
11.) Level B Hazmat suit
12.) Mission Oriented Protective Posture (MOPP) IV gear

- MCU 2/P Navy Gas Masks
- Gas Mask Hood
- MOPP Trousers
- MOPP Blouses
- MOPP Overboots
- MOPP Gloves

13.) Barrel Pump
14.) Eye Dropper
15.) Baking Soda
16.) HAZMAT Reference Book
17.) SteriFx Material Safety Data Sheets
18.) Hazardous Materials Spill Kit
19.) Fuller's Earth
20.) CleanseFx decontamination fluid (1X strength)
21.) Rinse Water
22.) Safety Goggles
23.) Heavy Plastic Gloves
24.) Funnel
25.) Batteries for Camera
26.) Plastic Washing Basin
27.) Plastic Shelving

Safety Precautions

1. The Decontamination Rinse Shower used in the process was new and had never been used for any chemical application.
2. The Principal Investigator was familiar with and followed the test guideline.
3. On the morning of 12 FEB 03, a meeting was held with the Hazardous Materials Waste Manager to discuss disposal of all training expendables. The discussion also touched on the prepositioning of smaller quantities of CleanseFx throughout the base. This was viewed as an interim decontamination quantity until larger quantities can be brought to the incident scene.
4. Medical personnel were on hand in the event of a heat-related emergency. First Aid Supplies (including Intravenous fluids) were available.

Set Up of Decon Area

1. Evolution area was located at a restriction (choke point) along the access road to the Naval Hospital. The purpose of the choke point was to allow security to effect riot control. This would restrict access to medical attention to only those personnel who had been decontaminated, and prevent the contamination of the health care area.

2. The evolution area was located across the road from the fire hydrant that supplied the water for the Decontamination Rinse Shower. Hose ramps were placed over the fire hose.
3. Rolled out polyethylene.
4. Marked off area with emergency barriers.
5. Placed cardboard trashcan on polyethylene at locations where clothing was removed.
6. Placed wading pools in decontamination area, and assembled the decontamination rinse shower.
7. Placed clean/new sprayer next to wading pool.
8. A decontamination team member was stationed at the wading pool area dressed in a Level B disposable suit.

Figure 9. Setup of the Decontamination Area

Results

Four Training sessions were held, and 46 people were trained in Patient/Personnel Decontamination with CleanseFx fluid. These people represented the U.S. Army, U.S. Navy, and the Guantanamo Bay, Cuba and Fairfax County Virginia Fire Departments. The military representatives came from several different places on the Naval Station. Their backgrounds ranged from Veterinary Services to Dental Corps.

The didactic portion of the training consisted of a Power Point[R] presentation with handouts. The Material Safety Data Sheet and Laboratory Results were provided. This was followed by a litmus paper test. Baking soda was placed on a small pool of CleanseFx on the hand. To make the point, a small amount of CleanseFx was orally ingested.

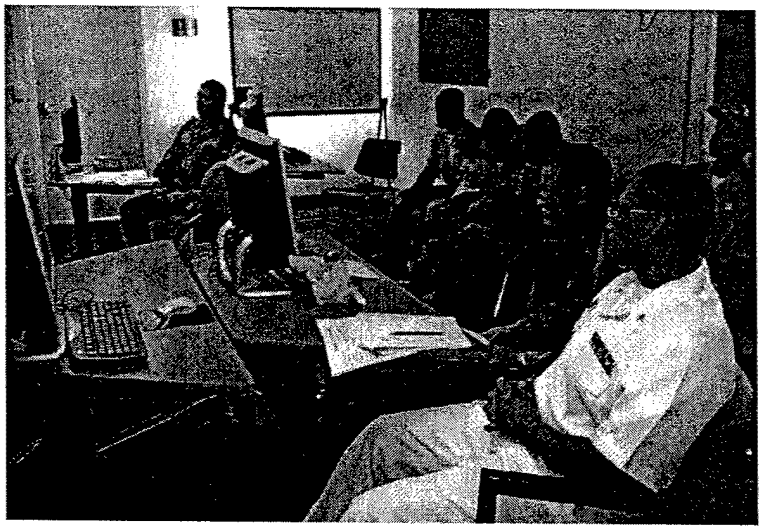


Figure 10. Class One, 13 FEB 03

The practical portion consisted of an instructor (a representative from the Navy) suiting up in Hazardous Material Operations Level B, and an instructor suiting up to MOPP level IV. Students were urged to put on the gear that they were most likely to use in an emergency situation. There were students that were curious about the other equipment, and they were encouraged to try it (if time permitted).

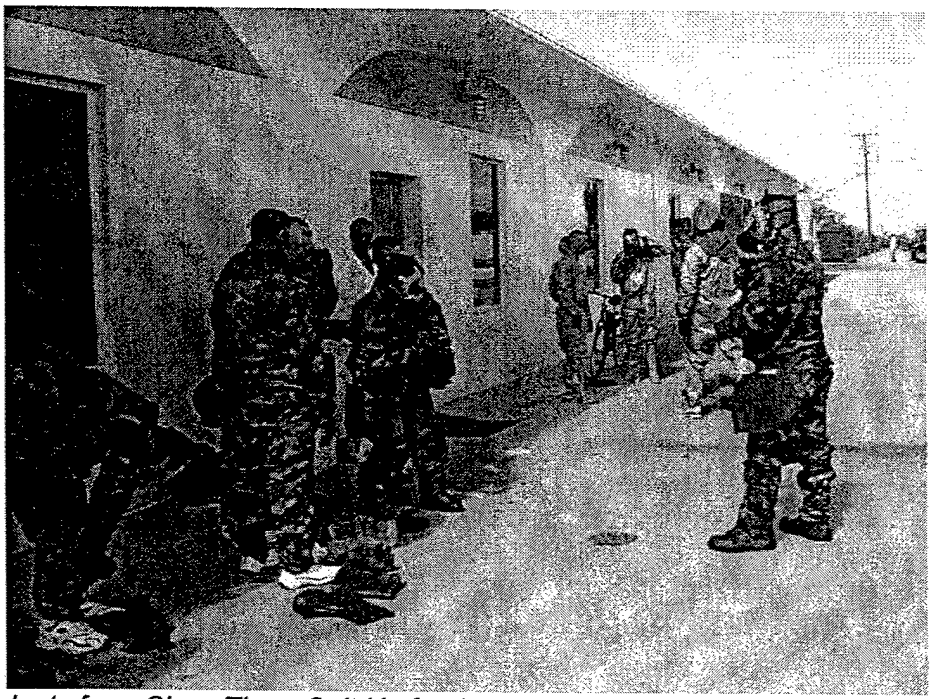


Figure 11. Students from Class Three Suit Up for the Practical Portion of the Training.

Students were lead to the decontamination site approximately 200 yards away while fully protected and masked. This was done to inspire confidence in them.

Figure 12. Instruction at Decontamination Site

Students were given the option to simulate decontamination with water, or undergo decontamination with live CleanseFx. Several chose to be decontaminated using the live fluid. Throughout all four training evolutions, personnel tried to closely match training to how the actual Emergency Plan would be followed. The motto was "Train Like You Fight, and Fight Like You Train."

Figure 13. A Student from Class Two Enters the Decontamination Rinse Shower

Student feedback was almost entirely positive. In fact, many other uses for CleanseFx were discussed. After discussion of the SteriFx equine research data, the students from the Veterinary Clinic obtained a sample for a canine patient that was having difficulty with opportunistic organisms attacking its skin. Cleaning surfaces that come in contact with food in the galley was discussed. Decontamination of emergency medical gear as well as the back of the ambulance was discussed as well. At least one in three people wanted to obtain a sample for their own personal use.

The only negative aspect of the Product Investigation was the lingering doubt that there must be some disadvantage to CleanseFx. Many students were incredulous that such a substance appeared to have very little disadvantage, and so many advantages. The confidence tests, outlined above, generally dispelled most negative thoughts.

Discussion and Conclusion

The Patient Decontamination Training conducted in Guantanamo Bay, Cuba, 11 - 15 February 2003 was extremely successful. The large quantity of enthusiastic, positive feedback from the customers, and the absence of any negative feedback all point toward customer satisfaction. This, coupled with the laboratory test data and the regulatory approvals point toward a successful transition. The transition of the Department of Defense from the age-old approach of sodium hypochlorite to a much safer and more effective decontamination fluid. CleanseFx is going to be accepted with much enthusiasm as the replacement for bleach on the battlefield.

This report is for SteriFx Inc. An additional report is being filed by Navy Personnel to summarize the results of the Product Investigation. The following was taken from an electronic mail message sent from Navy personnel to NMLC (a copy of the electronic mail was furnished to SteriFx):

"Results indicate that the candidate has some characteristics superior to the current product being used. CleanseFx did not bleach, discolor or stain anything. It was not corrosive to equipment or an irritant to the decontamination personnel. The current method uses STB which will bleach most fabrics and non-metallic equipment. STB is corrosive to equipment and is an irritant. It is our recommendation that STB be replaced with CleanseFx as a decontamination solution for use in deployed assets of the U.S. Navy."

The Navy results will be published within the next 6 weeks by NMLC. It was important that their conclusion be included in this report.

Appendix A

Naval Medical Logistics Command
Shipping, Storage and Handling Test

Candidate Decontaminant: CleanseFx		
Company Name: SteriFx, Shreveport, LA		
Receipt Location: Storage Area PREV MED	Date Inspected: 12 FEB 03	
Receiving Party: Preventive Medicine Department, Naval Hospital, Guantanamo Bay, Cuba		
	Acceptable	Unacceptable
1. Weight of the cargo distributed evenly over the floor of the container	X	
2. Cargo blocked and braced to prevent movement in any direction	X	
3. All supplies containing liquid are packaged in appropriate containers.	X	
4. Kept the center balance of the cargo as near as possible to the center of the container.	X	
5. Weight limitations of the container were not exceeded	X	
6. Containers weighed and recorded prior to shipment	X	
7. Procedures for hazardous cargo observed	X	
8. All contents stored upright	X	
9. Drums stowed with bungs uppermost	X	
10. Drums are new and not reused "single use"	X	
11. Adequate seals used on locking levers and sealing rings of open-end drums	X	
12. Drums approved for hazardous cargo	X	
13. Weight of cargo and dunnage does not exceed the container weight capacity and over-the-road limitations.	X	

ATTACHMENT I

Final Report Abstract: DARPA Contract No. DAAH01-02-C-R173 - ADDENDUM

SteriFx, Inc has demonstrated feasibility that our technology can provide an answer to the problem of biological decontamination based upon the properties of our new aqueous compound, CleanseFx. This proprietary compound is the basis for the development and commercialization of a line of antimicrobial and wound care products, even to include a cold sterilant. The compound is an aqueous acidic mixture with a pH of less than 1, normally considered toxic or dangerous, however the method of manufacture and final composition of the compound results in a solution that is acidic while retaining a large margin of safety. The low pH of the solution provides for an environment that destroys bacteria on living skin within minutes, without harming the host. This efficacy coupled with safety could provide a system for personnel and civilian decon. A military training mission demonstrating use was carried out, and indications are that CleanseFx was preferred over standard hypochlorite solutions that harm skin, eyes, clothes, as the hypochlorite label specifically prohibits use on human tissues. CleanseFx is currently marketed as an FDA-cosmetic product.

ATTACHMENT I