State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

May 8, 1996

Ms. Suzanne Helton Beck
Roatan Medical Services Corporation
1022 Santerre Drive
Grand Prairie, Texas 75050

Dear Suzanne:

Thank you for your application for approval of the Roatan steam sterilization unit. The unit offers a new approach to steam sterilization since it generates steam from the water in the waste load, avoiding cold spots. This is to request additional information for the approval process.

Steam sterilization is designated for microbiological waste in the North Carolina Medical Waste Management Rules. Approval is not required as long as the unit is operated as specified in the rules.

Steam sterilization deactivates microorganisms by exposure to moist heat for an adequate length of time. The North Carolina rules specify three minimum operating parameters for steam sterilizers - 15 psi, 250F, and a treatment time of 45 minutes. Units must monitor and record time and temperature throughout each cycle. Steam sterilizers may operate at alternative parameters if they are shown to be effective.

In the application for approval Roatan does not specify two of the three alternative parameters that will be used. The Roatan steam sterilization unit does not operate at a defined temperature or run time. These critical parameters are unknown and vary each run, depending on the composition and density of the waste load. Pressure is used as an indicator that an adequate temperature and run time have been achieved to deactivate microorganisms.

Since the more critical parameters of temperature and time are not known, and vary with each run, it is difficult to know if the unit will decontaminate waste under actual conditions, given the variability of waste loads. The North Carolina regulations emphasize maintaining minimal conditions which are shown in tests to be effective. As stated in a research paper by Rutala, Stiegel,and Sarubbi in 1982, "The decontamination of hazardous microbiological waste by steam sterilization is complex, for by varying test conditions, one can markedly alter the thermal and biological result. Unless specific minimal conditions are attained, bacterial will remain viable."

The Solid Waste Section wants to encourage development of new technologies and recognizes that new technologies will have innovative approaches and will not always fit routine descriptions and operating parameters.

Suggestions are:

- Define the minimal temperature and exposure time that correlate to pressure, and demonstrate that these conditions will always be met. You may already have some data from your earlier tests, since the report said temperature is monitored and data is stored on a disk. Such data could be graphed showing the relationship of pressure to temperature ranges and time.

- Consider installing an experimental unit in North Carolina to develop data to define the operating parameters.

Thank you for your application and I look forward to working on this further.

Sincerely,

Ernest Lawrence, Ph.D.
Environmental Biologist

North Carolina
Department of Environment and Natural Resources

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary
Dexter R. Matthews, Director

February 5, 2003

Sanford A. Glazer
Antaeus Group
3051 Washington Blvd
Baltimore, MD 21230

Dear Dr. Glazer:

This is in response to your request for approval of the SSM 150/75 processor for treatment of medical waste. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms in waste that was exposed to superheated water at temperatures an equivalent time of 250F for 30 minutes at variable psi. The unit is approved for microbiological waste as long as it is operated at least at the parameters represented in the test reports, including time, temperature, and load density. Operation of the unit outside parameters represented in the tests is not approved.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer and the sewer treatment authority is notified.

Microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402). Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

Any water and air emissions should comply with state and federal laws. Also, operation of the unit should be consistent with OSHA guidelines for handling and managing waste while it is in the workplace.

Prior to initiation of this treatment process notification must be made to the Solid Waste Section.

If you have questions please call me at 919-733-0692 ext.254 or Ernest Lawrence at ext. 274.

Sincerely,

Paul Crissman, Environmental Programs Manager
Special Waste Branch

North Carolina
Department of Environment and Natural Resources

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary
Dexter R. Matthews, Director

February 5, 2003

Sanford A. Glazer
Antaeus Group
3051 Washington Blvd
Baltimore, MD 21230

Dear Dr. Glazer:

This is in response to your request for approval of the SSM 150/75 processor for treatment of medical waste. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms in waste that was exposed to superheated water at temperatures an equivalent time of 250F for 30 minutes at variable psi. The unit is approved for microbiological waste as long as it is operated at least at the parameters represented in the test reports, including time, temperature, and load density. Operation of the unit outside parameters represented in the tests is not approved.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer and the sewer treatment authority is notified.

Microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402). Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

Any water and air emissions should comply with state and federal laws. Also, operation of the unit should be consistent with OSHA guidelines for handling and managing waste while it is in the workplace.

Prior to initiation of this treatment process notification must be made to the Solid Waste Section.

If you have questions please call me at 919-733-0692 ext.254 or Ernest Lawrence at ext. 274.

Sincerely,

Paul Crissman, Environmental Programs Manager
Special Waste Branch

North Carolina Department of Environment and Natural Resources

Dexter R. Matthews, Director

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary

January 2, 2007

Donii Fox, MSPH, CIH
Biological Safety Officer
University of North Carolina at Chapel
Department of Environment, Health, Safety
1120 Estes Drive Extension
Campus Box 1650
Chapel Hill, NC 27599-1650

Dear Donii Fox:

This is in response to your letter requesting approval of the chemical treatment of *P. aeruginosa, E. coli & Staph. aureus* using BacDown detergent disinfectant as described in the request for approval submitted to the Department.

According to 15A NCAC 13B .1207(4)(b) the Division is authorized to approve the alternative chemical treatments of microbiological wastes.

The chemical treatment of the organisms listed above as described in the procedures for treatment which was submitted with your letter of November 6, 2006, is approved.

The test descriptions and results which were submitted to the Department substantiate the efficacy of the treatment of the organisms with BacDown.

Should you have any questions regarding this matter you may contact me at (919) 508-8499 or Bill Patrakis at (919) 508- 8512.

Sincerely,

Ellen Lorscheider

Ellen Lorscheider
Environmental Programs Manager

Cc: Bill Patrakis, Environmental Biologist

1646 Mail Service Center, Raleigh, North Carolina 27699-1646
Phone: 919-508-8400 \ FAX: 919-733-4810 \ Internet: http://wastenotnc.org

North Carolina Department of Environment and Natural Resources

Dexter R. Matthews, Director

Division of Waste Management

Michael F. Easley, Governor

William G. Ross Jr., Secretary

February 26, 2007

Nelson S. Slavik, PhD
President
Environmental Health Management Systems, Inc.
2613 Skyway
Grand Prairie, Texas 75052

Re: Approval of the Oncore-MWP 2750

Dear Nelson S. Slavik;

This is in response to your letter requesting approval of the Oncore-MWP 2750 unit for treatment of regulated medical waste. The Oncore-MWP 2750 uses a combination of shredding and chlorine dioxide, at a minimal concentration of 350ppm for six minutes to treat regulated medical wastes.
Regulated medical waste is defined as pathological, microbiological, and containers of blood and body fluids in excess of 20ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste include items such as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required for such items before disposal in the general waste stream, therefore approval to treat such waste is not required by the Solid Waste Section.

In documents and test reports submitted to the Department, the Oncore MWP-2750 demonstrated effective treatment of test organisms. The unit is approved for the treatment of microbiological waste as long as the unit is operated in accordance with the manufacturer's stated procedures, parameters and maintenance schedules.

Pathological wastes, bulk blood and body fluids may not be processed through the unit as per the manufacturer's recommendations.
Pathological wastes are defined as the tissues, organs, and body parts of humans and the carcasses of animals known or suspected to have died from a disease which is transmissible to humans.

Should you have any questions regarding this matter you may contact me at (919) 508- 8499 or Bill Patrakis at 919-508-8512.

Sincerely,

Ellen Lorschieder

Ellen Lorschieder
Environmental Programs Manager
Solid Waste Section

Cc:file

1646 Mail Service Center, Raleigh, North Carolina 27699-1646
Phone 919-508-8400 \ FAX 919-733-4810 \ Internet http://wastenotnc.org

North Carolina Department of Environment and Natural Resources

Dexter R. Matthews, Director

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary

January 26, 2007

Donii Fox, MSPH, CIH
Biological Safety Officer
University of North Carolina at Chapel
Department of Environment, Health, Safety
1120 Estes Drive Extension
Campus Box 1650
Chapel Hill, NC 27599-1650

Dear Donii Fox:

This is in response to your letter requesting approval of the chemical treatment of *E. coli & Mycobacterium smegmatis* using Vesphene IIse Disinfectant Cleaner as described in the request for approval submitted to the Department.

According to 15A NCAC 13B .1207(4)(b) the Division is authorized to approve the alternative chemical treatments of microbiological wastes.

The chemical treatment of the organisms listed above as described in the procedures for treatment which was submitted with your letter of December 14th, 2006, is approved.

The test descriptions and results which were submitted to the Department substantiate the efficacy of the treatment of the organisms with Vesphene IIse.

Should you have any questions regarding this matter you may contact me at (919) 508-8499 or Bill Patrakis at (919) 508- 8512.

Sincerely,

Ellen Lorscheider

Ellen Lorscheider
Environmental Programs Manager

Cc:Bill Patrakis, Environmental Biologist

North Carolina Department of Environment and Natural Resources

Dexter R. Matthews, Director

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary

January 2, 2007

Don Cox, President/CEO
Diane Gorder, Director of Regulatory Compliance
BioMedical Technology Solutions, Inc.
9800 Mt. Pyramid Court, Suite 350
Englewood, Colorado 80112

Dear Don Cox and Diane Gorder;

This letter is in response to your letter requesting transfer of the Demolizer™ approval from Thermal Waste Technologies, Inc. to BioMedical Waste Technology Solutions.

The transfer of approval is granted and is contingent on the basis that the technology and the treatment process have not been substantially altered and that the technology continues to adhere to conditions and guidelines set forth in the original approval issued February 2, 1994.

Should you have any concerns or questions regarding this matter I may be reached at 919-508-8499 or Bill Patrakis at 919-508-8512.

Sincerely,

Ellen Lorscheider

Ellen Lorscheider
Environmental Programs Manager

Cc: Bill Patrakis, Environmental Biologist

1646 Mail Service Center, Raleigh, North Carolina 27699-1646
Phone 919-733-4996 \ FAX 919-715-3605 \ Internet http://wastenotnc.org

North Carolina Department of Environment and Natural Resources

Dexter R. Matthews, Director **Division of Waste Management**

Michael F. Easley, Governor
William G. Ross Jr., Secretary

January 2, 2007

Donii Fox, MSPH, CIH
Biological Safety Officer
University of North Carolina at Chapel
Department of Environment, Health, Safety
1120 Estes Drive Extension
Campus Box 1650
Chapel Hill, NC 27599-1650

Dear Donii Fox:

This is in response to your letter requesting approval of the chemical treatment of *Dengue Fever* virus using bleach as described in the request for approval submitted to the Department.

According to 15A NCAC 13B .1207(4)(b) the Division is authorized to approve the alternative chemical treatments of microbiological wastes.

The chemical treatment of *Dengue Fever* virus as described in the procedures for treatment which was submitted with your letter of December 18, 2006, is approved.

The test descriptions and documents which were submitted to the Department substantiate the efficacy of the treatment of the organism with bleach.

Should you have any questions regarding this matter you may contact me at (919) 508-8499 or Bill Patrakis at (919) 508- 8512.

Sincerely,

Ellen Lorscheider

Ellen Lorscheider
Environmental Programs Manager

Cc: Bill Patrakis, Environmental Biologist

NCDENR

NORTH CAROLINA DEPARTMENT OF
ENVIRONMENT AND NATURAL RESOURCES

DIVISION OF WASTE MANAGEMENT

JAMES B. HUNT JR.
GOVERNOR

BILL HOLMAN
SECRETARY

WILLIAM L. MEYER
DIRECTOR

April 12, 2000

Frank Stanton, R.S., HEM
Director of Regulatory Affairs
Isolyser
4320 International Blvd
Norcross, GA 30093

Dear Mr. Stanton:

This is in response to your question about the status of the 1989 approval letter to Isolyzer regarding your system for treatment and encapsulation of medical waste sharps. Sharps may continue to be treated and disposed in the landfill as the approval letter describes.

Please let me know if you have further questions.

Sincerely,

Ernest Lawrence, Ph.D.
Environmental Biologist

1646 MAIL SERVICE CENTER, RALEIGH, NORTH CAROLINA 27699-1646
401 OBERLIN ROAD, SUITE 150, RALEIGH, NC 27605
PHONE 919-733-4996 FAX 919-715-3605

North Carolina
Department of Environment and Natural
Resources

Michael F. Easley, Governor
William G. Ross Jr., Secretary
Dexter R. Matthews, Director

May 20, 2003
William D. Norton
WPS Company
Suite B
3051 Washington Blvd.
Baltimore, MD 21230

Dear Mr. William Norton

This is in response to the request for approval of the SSM 150/75 processor for treatment of medical waste. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms in waste that was exposed to superheated water at temperatures an equivalent time of 250F for 30 minutes at variable psi. The unit is approved for microbiological waste as long as it is operated at least at the parameters represented in the test reports, including time, temperature, and load density. Operation of the unit outside parameters represented in the tests is not approved.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer and the sewer treatment authority is notified.

Microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402). Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

Any water and air emissions should comply with state and federal laws. Also, operation of the unit should be consistent with OSHA guidelines for handling and managing waste while it is in the workplace.

Prior to initiation of this treatment process notification must be made to the Solid Waste Section.

If you have questions please call me at 919-733-0692 ext.254 or Ernest Lawrence at ext. 274.

Sincerely,

Paul Crissman, Environmental Programs Manager

Approved file

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

July 27, 1995

Dr. Nancy L. Davis
Research Associate Professor of Microbiology and Immunology
UNC - CH The School of Medicine
Campus Box No. 7290, 804 FLOB
Chapel Hill, NC 27599-7290

Dear Dr. Davis:

This is in response to your letter regarding chemical treatment of wastes containing Venezuelan equine encephalitis virus.

The Division is authorized to approve chemical treatment of microbiological waste in accordance with 15A NCAC 13B .1207(4)(b).

The chemical treatment of virus-contaminated waste as described in your letter on July 17, 1995 is approved as an appropriate treatment method.The waste which has been treated in this manner would no longer be classified as regulated medical waste.

The treated waste may have other characteristics that require special management, but are not covered by the medical waste management regulations. Please manage and dispose the waste in accordance with regulations of the Division of Radiation Protection if the waste is radioactive at a level of regulatory concern. If the waste contains RCRA regulated chemicals please abide by the applicable regulations.

This approval does not not imply a review or endorsement of containment practices or other biosafety procedures. The virus should be managed in accordance with guidelines of the CDC/NIH and other applicable agencies.

If you have further questions please call the Solid Waste Section at 919-733-0692.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc: Ernest Lawrence

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

August 12, 1997

R. D. Tilbury
President
XOLO, INC.
16631 Manningtree Lane
Spring, Texas 77379

Dear Mr. Tilbury:

This is in response to your request for approval of the Environmental Waste Management Corporation (EWMC) MD-1000 Medical Waste Reduction System unit for treatment of regulated medical waste. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is <u>not</u> regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms which were exposed to microwave energy generating temperatures of 72 - 210 C for 60 - 70 minutes. The unit is approved for microbiological waste as long as it is operated at parameters of time/temperature/pressure/load density/microwave energy as represented in the test reports. Operation of the unit outside parameters represented in the tests is not approved.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer and the sewer treatment authority is notified. Pathological waste may not be processed by this unit and must be incinerated.

The unit should be tested for effectiveness of treatment as recommended by the manufacturer. This includes testing 20 biological indicators each three months.

Microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402 Stock #17-40-508-3.) Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

P.O. Box 27687,
Raleigh, North Carolina 27611-7687
Voice 919-733-4996

NC Reduce Reuse Recycle

FAX 919-715-3605

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

May 24, 1996

Randall G. McKee
223 S. West Street
Lebanon, IN 46052

Dear Mr. McKee:

This is in response to your letter requesting approval of the STI Chem-Clav unit for treatment of regulated medical waste, using a combination of shredding, chemical treatment, and heat treatment. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms which were exposed to 1000 ppm sodium hypochlorite for 10 minutes and temperatures of 205-210 F for 30 minutes. The unit is approved for microbiological waste as long as it is operated at these parameters or higher and as represented in the test reports.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer. The application stated that the unit was appropriate for pathological waste, but did not include information to support this. Pathological waste may not be processed by this unit and must be incinerated.

The unit should be tested for effectiveness of treatment using biological indicators weekly as recommended by the manufacturer.

Any water and air emissions should comply with state and federal laws. Also, operation of the unit should be consistent with OSHA guidelines for handling and managing waste while it is in the workplace.

Prior to initiation of this treatment process notification must be made to the Solid Waste Section, attention Ernest Lawrence.

If you have questions please call 919-733-0692 ext.274.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

North Carolina
Department of Environment and Natural Resources

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary
Dexter R. Matthews, Interim Director

September 18, 2001

Joseph H. Wilson
President and CEO
Waste Reduction by Waste Reduction, Inc
5711 W. Minnesota Street
Indianapolis, IN 46241

Dear Mr. Wilson:

This is in response to your request for approval of the WR2 100 Tissue Digestor for treatment of regulated medical waste. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms in waste that was exposed to an alkaline solution and a temperature of 245F at 16 psi for 3 hours. The unit is approved for all regulated medical waste as long as it is operated at the parameters represented in the test reports, including time, temperature, chemical concentration, and load density. Operation of the unit outside parameters represented in the tests is not approved.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer and the sewer treatment authority is notified.

Microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402). Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

Any water and air emissions should comply with state and federal laws. Also, operation of the unit should be consistent with OSHA guidelines for handling and managing waste while it is in the workplace.

Prior to initiation of this treatment process notification must be made to the Solid Waste Section, attention Ernest Lawrence.

If you have questions please call 919-733-0692 ext.274.

Sincerely,

Paul Crissman

Paul Crissman, Supervisor
Special Waste Branch

1646 Mail Service Center, Raleigh, North Carolina 27699-1646
Phone: 919-733-0692 \ FAX: 919-733-4810 \ Internet: www.enr.state.nc.us/

North Carolina
Department of Environment and Natural Resources

Division of Waste Management

Michael F. Easley, Governor
William G. Ross Jr., Secretary
Dexter R. Matthews, Director

August 7, 2002

Donald L. Smith, President
Environmental Disposal Solutions, Inc
PO Box 6703
Greenville, SC 29606

Dear Mr. Smith:

This is in response to your request for approval of the EDS P-3000 processor for treatment of medical waste. Regulated medical waste is pathological waste, microbiological waste, and containers of blood and body fluids in excess of 20 ml (eg. operating room suction canisters).

Medical waste that is not regulated medical waste includes such items as used gloves, bloody gauze, bloody dressings, and sharps. No treatment is required before disposal in the general waste stream, so approval to treat such waste is not required by the Solid Waste Section.

In test reports submitted, the unit achieved high efficacy on test organisms in waste that was exposed to superheated water at temperatures of 253-257F at 18.1-22 psi for 10 minutes. The unit is approved for microbiological waste as long as it is operated at least at the parameters represented in the test reports, including time, temperature, and load density. Operation of the unit outside parameters represented in the tests is not approved.

Blood and body fluids in volumes greater than 20 ml per individual container may be processed through the unit only if free liquids are ultimately discharged into the sanitary sewer and the sewer treatment authority is notified.

Microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402). Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

Any water and air emissions should comply with state and federal laws. Also, operation of the unit should be consistent with OSHA guidelines for handling and managing waste while it is in the workplace.

Prior to initiation of this treatment process notification must be made to the Solid Waste Section, attention Ernest Lawrence.

If you have questions please call me at 919-733-0692 ext.254 or Ernest Lawrence at ext. 274.

Sincerely,

Paul Crissman

Paul Crissman, Environmental Programs Manager
Special Waste Branch

State of North Carolina
Department of Environment, Health, and Natural Resources
512 North Salisbury Street • Raleigh, North Carolina 27604

James B. Hunt, Jr., Governor

SOLID WASTE MANAGEMENT DIVISION
TELEPHONE: (919) 733-0692

Jonathan B. Howes, Secretary

April 22, 1993

Dr. Sheri M. Nutter
Plaza Veterinary Clinic
104-M Carrboro Plaza
Carrboro, NC 27510-0031

Dear Dr. Nutter:

This is in response to your letter regarding chemical treatment of fungal cultures.

In accordance with 15A NCAC 13B .1207(4)(a), household bleach is appropriate for treating microbiological waste:

> "Cultures of throat, urine, sputum, skin and genitourinal tract which contain only the following organisms; N. gonorrhea, E. coli, staphylococcus, proteus, Candida albicans, B. cereus or normal flora in individual plates or tubes containing 5-20 ml media shall be covered, for a minimum of one hour, with a 1:5 dilution of household bleach (5.25% sodium hypochlorite) in water. The solution shall remain on the treated plates which are to be stacked in a plastic bag prior to disposal. The bag is to be sealed to prevent leakage."

The Division is authorized to approve other types of chemical treatment in accordance with .1207(3)(b).

Treatment of cultures using a 1:5 dilution of household bleach (10,000 ppm) for 1 hour is an appropriate treatment method for the common ringworm organism Trichophyton and Microsporum.

If you have further questions please call the Solid Waste Section at 919-733-0692.

Sincerely,

Ernest Lawrence

Ernest Lawrence, Ph.D.
Environmental Specialist

P.O. Box 27687, Raleigh, North Carolina 27611-7687 Telephone 919 733-4984 Fax # 919-733-0513

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

December 17, 1990

Robert E. Williams
Clinton Medical Clinic
403 Fairview Street
Clinton, NC 28328

Dear Mr. Williams:

The Solid Waste Section has reviewed your request to use the treatment procedure described in 15A NCAC 13B .1207(4)(a) for the treatment of cultures containing the following:

Psuedomonas	Klebsiella
Enterobacter	Serratia
Yersinia	Cirtobacter

The Agency has determined that this is an appropriate method of treatment for the aforementioned cultures. If you have further questions regarding medical waste, please contact Dee Eggers at (919) 733-0692.

Sincerely,

Dee Eggers,
Environmental Specialist

dme

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

November 30, 1990

Dr. Rebecca King
Division of Dental Health
PO Box 27687
Raleigh, NC 27611-7687

Dear Dr. King:

I am writing in response to your request for information on the proper disposal of extracted teeth. The Solid Waste Management Division does not require treatment or packaging of extracted teeth prior to disposal.

If you have further question, please contact Dee Eggers at 733-0692.

Sincerely,

William L Meyer

William Meyer, Chief
Solid Waste Management Division

dme

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

September 24, 1990

Stephen R. Stribley
Marketing Coordinator
8100 South Akron St.
Englewood, CO 80112-6604

Dear Mr. Stribley:

The Solid Waste Section has reviewed the information you submitted on the Disposal Sciences, Incorporated Sharps Disposal System. In North Carolina, sharps which are not packaged prior to disposal must be rendered unrecognizable. The sample "puck" submitted as a representative demonstrates that the system is capable of rendering sharps unrecognizable. Provided the system achieves a similar level of unrecognizability in a commercial setting, it is approved for use in North Carolina.

North Carolina does not currently require treatment for sharps. Accordingly, the Section does not approve sharps "treatment" systems.

If you have further questions, please contact Dee Eggers at (919) 733-0692.

Sincerely yours,

J. Gordon Layton, Chief
Solid Waste Section

dme

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

September 13, 1990

Rebecca R. Zepeda
Eastover Internal
Medicine Associates, P.A.
491 North Wendover Rd.
Charlotte, NC 28211

Dear Ms. Zepeda:

The Department of Environment, Health, and Natural Resources and the University of North Carolina's Statewide Infection Control Program have reviewed your request to use the treatment procedure described in 15A NCAC 13B .1207(4)(a) for the treatment of cultures containing streptococcus. Both agencies have determined that this is an appropriate method of treatment for the aforementioned cultures.

If you have further questions regarding medical waste, please contact Dee Eggers at (919) 733-0692.

Sincerely,

J. Gordon Layton, Chief
Solid Waste Section

dme

THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

School of Medicine
Department of Medicine
Division of Infectious Diseases

Main Office: (919) 966-2536
Infection Control: (919) 966-3242
FAX: (919) 966-6714

CB# 7030, 547 Burnett-Womack
The University of North Carolina at Chapel Hill
Chapel Hill, N.C. 27599-7030

August 31, 1990

Dee Eggers
Environmental Specialist
Solid Waste Section
P. O. Box 27687
Raleigh, NC 27611-7687

Dear Dee:

This letter is in regards to our telephone conversation concerning the treatment of culture plates containing streptococcus in accordance with 15A NCAC 13G.1207 (A)(a). Essentially all microorganisms recovered on growth media can be treated by a number of high-level disinfectants in addition to that described in the current North Carolina Register on Medical Waste Management. Therefore, in the opinion of the Statewide Infection Control Program, streptococcus is not unlike those organisms listed in the above document in regards to chemical inactivation and may be included in the stated list.

Sincerely,

Karen K. Hoffmann, R.N., M.S., C.I.C.
Director, Statewide Infection Control Program

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

May 7, 1990

Harry Hauser
Director of Engineering
Forsyth Memorial Hospital
3333 Silas Creek Parkway
Winston-Salem, NC 27103

Subject: Approval of the Vetco Sanitec unit for treatment of infectious medical waste

Dear Mr Hauser:

The North Carolina Solid Waste Section of the Department of Environment, Health, and Natural Resources has reviewed the submitted information. Based on this information, we approve of the Vetco Sanitec infectious waste treatment system as a suitable method of treatment of infectious waste for ultimate disposal as provided under North Carolina Solid Waste Management Rules 10 NCAC 10G. This approval is in response to requests received from Forsyth Memorial Hospital. This approval is subject to the following conditions:

1. Forsyth Memorial Hospital shall log and maintain testing results of microbiological disinfection testing conducted as described in section B(3) of the Vetco Sanitec Hospital Waste Disinfection Unit Performance Testing Protocol. Changes to the protocal must be approved by the Division.
2. Use of this product is restricted to treatment and disposal of pathological, microbiological and general solid waste, excluding sharps and liquid waste. Treatment of any waste generated off-site will require a permit issued by the Division.
3. Use of this unit is contingent upon maintaining records demonstrating that at least the degree of disinfection upon which this approval is based is sustained.
4. This approval shall be valid until such time as new regulations are in effect or it is determined that this technology no longer meets the requirements of the regulations.

THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

School of Medicine
Department of Medicine
Division of Infectious Diseases

Main Office: (919) 966-2536
Infection Control: (919) 966-3242
FAX: (919) 966-6714

CB# 7030, 547 Burnett-Womack
The University of North Carolina at Chapel Hill
Chapel Hill, N.C. 27599-7030

April 19, 1990

Ms. Dee Eggers
N. C. Solid Waste Management
401 Oberlin Road
P. O. Box 27687
Raleigh, NC 27611-7687

Dear Dee:

The purpose of this letter is to document our conversation regarding the use of spores of B. subtilis for monitoring a microwave waste disinfection procedure. The most conservative approach for monitoring a waste disinfection procedure, which provides an exceptional margin of safety, would involve the use of biological indicators such as spores of B. subtilis. This practice may be viewed by some as unrealistic and the argument raised that it is not necessary to ensure the elimination of bacterial spores in such a process. As you know, "treatment" is described in the Medical Waste Tracking Act as "any method, technique, or process designed to change the biological character or composition of medical waste so as to eliminate or reduce its potential for causing disease."

I hope the enclosed information is helpful; please don't hesitate to contact me if you need additional assistance.

Sincerely,

William A. Rutala, Ph.D., M.P.H.
Research Associate Professor
Director, Statewide Infection Control Program

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

October 13, 1989

Mr. Travis W. Honeycutt, Exec. V.P.
ISOLYSER
4350 International Blvd., NW
Norcross, Georgia 30093

Subject: Approval of the ISOLYSER System for Chemical Disinfection and Encapsulation for Disposal of Medical Waste Sharps

Dear Mr. Honeycutt:

The North Carolina Solid Waste Section of the Department of Environment Health and Natural Resources (DEHNR) has reviewed the submitted information and chemically analyzed the gel sample supplied by ISOLYSER. Based on these findings, we approve of the ISOLYSER medical waste treatment system as a suitable method of treatment and containerization of medical waste sharps for ultimate disposal as provided under North Carolina Solid Waste Management Rules 10 NCAC 10G. This approval is in response to requests received from Clair M. Coppage dated May 19, 1989 and subsequently from you on July 11, 1989. This approval is subject to the following conditions:

1. ISOLYSER will provide, when requested by the N.C. DEHNR, lists of the distributors and users of this product as well as approximate volumes being utilized within the State of N.C.
2. Use of this product is restricted to treatment and disposal of medical waste sharps.
3. Usage of this system is contingent upon maintaining the containerization and concentrations of materials evaluated for this approval. No free liquids are to be present at disposal.
4. This approval shall be valid until such time as new regulations are in effect or until such time it is determined that this technology no longer meets the requirements of the regulations.

Disposal of containers which have been carried through the final gelling step are approved for inclusion with routine solid waste. This will allow disposal without utilizing the formal request requirement of "Procedure and Criteria for Waste Determination" specified in 10 NCAC 10G.

If you have any questions, please contact me at (919) 733-0692.

Sincerely,

J. Gordon Layton, Chief
Solid Waste Section

JGL/mj

North Carolina Department of Human Resources
Division of Health Services
P.O. Box 2091 • Raleigh, North Carolina 27602-2091

James G. Martin, Governor
Phillip J. Kirk, Jr., Secretary

Ronald H. Levine, M.D., M.P.H.
State Health Director
919/733-3446

May 28, 1985

M E M O R A N D U M No. 3

TO: Mildred A. Kerbaugh, Chief
Laboratory Section

FROM: William L. Meyer, Head
Solid & Hazardous Waste Management Branch
Environmental Health Section

SUBJECT: APPROVED METHOD FOR TREATMENT OF CULTURES OF N. GONORRHOEAE, E. COLI, STAPHYLOCOCCUS, PROTEUS, CANDIDA ALBICANS, B. CEREUS PRIOR TO DISPOSAL IN SANITARY LANDFILLS.

In accordance with .0107 (b) of the Solid Waste Management Rule's the procedure as specified in your memorandum of March 26, 1985 is approved.

This procedure may be issued to treat the referenced infectious waste prior to disposal in a sanitary landfill. It will be the responsibility of each laboratory to ensure that this procedure is followed and the infectious waste is rendered non-infectious.

WLM/plg

ENCLOSURE:

State of North Carolina
Department of Environment,
Health and Natural Resources

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary

DEHNR

November 10, 1993

Suzanne E. Helton
ABB Sanitec, Inc.
Wayne Interchange Plaza II
155 Route 46 West
Wayne, New Jersey 07470

Dear Ms. Helton:

This is in response to your request for approval of for the ABB Sanitec Microwave Disinfection System as an acceptable method of treatment of blood and body fluids in individual containers in volumes greater than 20 mL.

The Division of Solid Waste Management has completed its review of the submitted data, including the tests showing efficacy under conditions of high moisture loading (50%) and high organic loading (70%).

As provided for in 15A NCAC 13B in 1203(b) this process is approved statewide for the treatment of blood and body fluids in containers in volumes greater than 20 mL and is subject to the conditions herein.

CONDITIONS TO COMPLY WITH APPROVAL:

1. Prior to initiation of operation of this process notification must be sent to the NC Solid Waste Section.

2. The system must meet all operational requirements stated in 15A NCAC 13B .1207(5) "Microwave treatment requirements."

3. The system shall be operated consistent with manufacturers' specifications and in such a manner as to assure reliable decontamination of the waste to levels represented by the submitted test data.

4. An operations log indicating operating conditions must be maintained and available for inspection by local health department officials and representatives of the Division of Solid Waste Management.

5. Processed wastes must be dewatered to the extent they will pass the paint filter liquids test prior to transportation to a waste disposal facility.

6. This approval does not relieve an owner/operator of this process from obtaining other federal, state, or local permits as necessary.

This approval and conditions herein are valid until such time as it has been determined that the technology for this treatment no longer meets the requirements of the rules regarding the regulation and treatment of medical waste.

If you have questions please call the Section at 919-733-0692.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc: Ernest Lawrence

State of North Carolina
Department of Environment,
Health and Natural Resources

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

November 23, 1993

Mr. Theodore M. DuBose, IV
SafeWaste Corporation
13801 Reese Boulevard West
Suite 190
Huntersville, NC 28078

Dear Mr. DuBose:

This is in response to your letter regarding testing microwave medical waste treatment systems. As stated in 15A NCAC 13B .1207(5)(c) "Testing shall be performed no less than once per week or as specified by the Division."

The manufacturer's recommendation of monthly testing the first six months, and quarterly thereafter is an acceptable schedule provided that continuous monitoring demonstrate that time/temperature requirements are met.

Weekly testing should be conducted the first month of start-up of new units. Weekly testing should be continued if there is any variation from the required time/temperature parameters.

Thank you for your attention to this.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc Ernest Lawrence

P.O. Box 27687, Raleigh, North Carolina 27611-7687 Telephone 919-733-0692 FAX 919-733-4810

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary

DEHNR

September 21, 1993

Gale Flinchum
Pathology Coordinator, Microbiology
Carolina Medicorp, Inc
3333 Silas Creek Parkway
Winston-Salem, NC 27103

Dear Ms. Flinchum:

This is in response to your letter about use of Attest biological indicators to test the ABB Microwave Disinfecting System. As stated in 15A NCAC 13B .1207(5)(c):

"Monitoring under conditions of full loading for effectiveness of treatment shall be performed through the use of a biological indicator or other methods approved by the Division."

Enclosed biological indicators are routinely used to test sterilization processes, such as steam sterilizers. The 3M Attest is recommended by ABB Sanitec in their "Challenge Protocol - ABB Sanitec Microwave Disinfection Unit."

The 3M Attest is appropriate since it contains a mean population of 10^6 colony forming units of spores of Bacillus subtilis var. niger.

Sincerely,

Ernest Lawrence

Ernest Lawrence, Ph.D.
Environmental Specialist

P.O. Box 27687, Raleigh, North Carolina 27611-7687 Telephone 919-733-4996 FAX 919-733-4810

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

July 27, 1995

Dr. Nancy L. Davis
Research Associate Professor of Microbiology and Immunology
UNC - CH The School of Medicine
Campus Box No. 7290, 804 FLOB
Chapel Hill, NC 27599-7290

Dear Dr. Davis:

This is in response to your letter regarding chemical treatment of wastes containing Venezuelan equine encephalitis virus.

The Division is authorized to approve chemical treatment of microbiological waste in accordance with 15A NCAC 13B .1207(4)(b).

The chemical treatment of virus-contaminated waste as described in your letter on July 17, 1995 is approved as an appropriate treatment method.The waste which has been treated in this manner would no longer be classified as regulated medical waste.

The treated waste may have other characteristics that require special management, but are not covered by the medical waste management regulations. Please manage and dispose the waste in accordance with regulations of the Division of Radiation Protection if the waste is radioactive at a level of regulatory concern. If the waste contains RCRA regulated chemicals please abide by the applicable regulations.

This approval does not not imply a review or endorsement of containment practices or other biosafety procedures. The virus should be managed in accordance with guidelines of the CDC/NIH and other applicable agencies.

If you have further questions please call the Solid Waste Section at 919-733-0692.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc: Ernest Lawrence

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

May 7, 1990

Harry Hauser
Director of Engineering
Forsyth Memorial Hospital
3333 Silas Creek Parkway
Winston-Salem, NC 27103

Subject: Approval of the Vetco Sanitec unit for treatment of infectious medical waste

Dear Mr Hauser:

The North Carolina Solid Waste Section of the Department of Environment, Health, and Natural Resources has reviewed the submitted information. Based on this information, we approve of the Vetco Sanitec infectious waste treatment system as a suitable method of treatment of infectious waste for ultimate disposal as provided under North Carolina Solid Waste Management Rules 10 NCAC 10G. This approval is in response to requests received from Forsyth Memorial Hospital. This approval is subject to the following conditions:

1. Forsyth Memorial Hospital shall log and maintain testing results of microbiological disinfection testing conducted as described in section B(3) of the Vetco Sanitec Hospital Waste Disinfection Unit Performance Testing Protocol. Changes to the protocal must be approved by the Division.
2. Use of this product is restricted to treatment and disposal of pathological, microbiological and general solid waste, excluding sharps and liquid waste. Treatment of any waste generated off-site will require a permit issued by the Division.
3. Use of this unit is contingent upon maintaining records demonstrating that at least the degree of disinfection upon which this approval is based is sustained.
4. This approval shall be valid until such time as new regulations are in effect or it is determined that this technology no longer meets the requirements of the regulations.

Disposal of infectious waste treated by the Vetco Sanitec is approved for inclusion with routine solid waste. This will allow disposal without utilizing the formal request requirement of "Procedure and Criteria for Waste Determination" specified in 10 NCAC 10G.

If you have any questions, please contact me at (919) 733-0692.

Sincerely,

J. Gordon Layton, Chief
Solid Waste Section

dme

cc: Julian Foscue
Jeff Rogers
Don Smith

State of North Carolina
Department of Environment, Health, and Natural Resources
Division of Solid Waste Management
P.O. Box 27687 · Raleigh, North Carolina 27611-7687

James G. Martin, Governor
William W. Cobey, Jr., Secretary

William L. Meyer
Director

May 8, 1990

Harry Hauser
Director of Engineering
Forsyth Memorial Hospital
3333 Silas Creek Parkway
Winston-Salem, NC 27103

SUBJECT: Clarification of Approval of the Vetco Sanitec Unit for Treatment of Pathological Waste

Dear Mr. Hauser:

In the Solid Waste Section's approval for use of the referenced technology for treatment of medical waste, the treatment of pathological waste is approved as a treatment method prior to incineration. Pathological waste will require incineration prior to final disposal. The Section will consider subclasses of pathological wastes for the Vetco Sanitec Unit treatment only, if this is desired. This treatment methodology is consistent with our current Solid Waste Management Rules.

This clarifies the May 7, 1990 approval of the Vetco Sanitec Unit. If you have any further questions, please contact me at (919) 733-0692.

Sincerely,

J. Gordon Layton, Chief
Solid Waste Section

JGL/th

cc: Julian Foscue
Jeff Rogers
Dan Miles

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

April 26, 1994

Lauraine A. Segna
Applied Environmental, Inc.
11800 Sunrise Valley Drive, Suite 1200
Reston, VA 22091

Dear Ms. Segna:

This is in response to your letter requesting approval for treatment of medical waste with sodium hypochlorite. The regulations state that treatment with 1 percent sodium hypochlorite is acceptable for cultures from samples of the throat, urine, sputum, skin and genitourinal tract. This only applies to the following organisms;

"...N. gonorrhea, E. coli, staphylococcus, proteus, Candida albicans, and B. cereus or normal flora in individual plates or tubes containing 5-20 mL media..."

Other types of chemical treatment must be obtained from the Division. As stated in 15A NCAC 13B .1207 (4)(b);

" Request for approval must be substantiated by results of demonstrated effectiveness of the chemical to treat the specific microbiological agent(s) of concern for the waste disposed. Consideration must be given to such factors as temperature, time of contact, pH, concentration and the presence and state of dispersion, penetrability and reactivity of organic material at the site of application."

Your letter references OSHA and CDC acceptance of 1 percent sodium hypochlorite for disinfection of environmental surfaces. Please note that EPA registration of disinfectants is based on surface treatment only of smooth, pre-cleaned surfaces, which do not have organic matter present. These chemicals are not registered for decontamination of medical waste.

Please provide additional information which will better demonstrate effectiveness to treat the specific microbiological agent(s) of concern. This may be test data or previously published information that supports this. Also, please submit information which addresses the other above factors.

Please call 919-733-0692 if you have other questions.

Sincerely,

Ernest Lawrence, Ph.D.
Environmental Biologist

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

February 2, 1994

Mr. Jonathan Bricken
D.O.C.C. Inc.
240 East 76th Street
New York, NY 10021

Dear Mr. Bricken:

This is in response to your request for approval of the Demolizer as an alternative method for treating medical waste.

Only a portion of the medical waste stream is classified as regulated medical waste and is subject to treatment requirements. In accordance with 15A NCAC 13B .1201 (9) regulated medical waste means blood and body fluids in individual containers in volumes greater than 20 mL, microbiological waste, and pathological waste.

The North Carolina Medical Waste Management regulations do not require treatment of non-regulated medical waste, such as sharps, bloody gauze and dressings, bandaids, tubing, and used gloves. These items can be landfilled untreated under North Carolina regulations. There are no EPA or OSHA regulations that prohibit landfill disposal of untreated non-regulated medical waste in North Carolina. If non-regulated medical waste is treated in the unit, the conditions herein must be met.

As provided for in 15A NCAC 13B in 1203(b) this process is approved for the treatment of microbiological waste subject to the conditions herein.

Please note that microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402 Stock #17-40-508-3.) Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

CONDITIONS TO COMPLY WITH APPROVAL:

1. Prior to initiation of operation of this process notification must be sent to the NC Solid Waste Section.

P.O. Box 27687, Raleigh, North Carolina 27611-7687 Telephone 919-733-4996 FAX 919-715-3605

2. If the system produces liquid discharges, notification of this waste management practice shall be made to the wastewater/sanitary sewer authority serving the facility where the equipment is installed prior to any discharge. All discharges must comply with pretreatment requirements.

3. The system shall be operated consistent with manufacturers' specifications and in such a manner as to assure reliable decontamination of the waste to levels represented by the submitted test data.

4. An operations log indicating operating conditions must be maintained and available for inspection by local health department officials and state environmental and health officers.

5. The treatment of sharps by this process must be accomplished in such a fashion that renders the sharps unrecognizable as to their former function. If this is not achieved, the processed waste will be subject to a packaging requirement, using a puncture-resistance container.

6. Processed wastes must be dewatered to the extent they will pass the paint filter liquids test prior to transportation to a waste disposal facility.

7. Prior to operating a facility, a Solid Waste Permit shall be required in accordance with the Solid Waste Management Rules if off-site waste is to be received.

8. This approval does not relieve an owner/operator of this process from obtaining other federal, state, or local permits as necessary.

This letter does not constitute approval to treat pathological waste or blood and body fluids. Existing treatments for these wastes are readily available and meet the state goals regarding waste management.

This approval and conditions herein are valid until such time as it has been determined that the technology for this treatment no longer meets the requirements of the rules regarding the regulation and treatment of medical waste.

If you have questions please call the Section at 919-733-0692.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc Ernest Lawrence

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary
William L. Meyer, Director

DEHNR

October 24, 1994

Dr. John H. Keene
Biohaztec Associates, Inc.
924 Castle Hollow Road
Midlothian, VA 23113

804-379-9192

Dear Dr. Keene:

This is in response to your request for approval of the Bioconversion Technologies, Inc. treatment system as an alternative method for treating regulated medical waste.

Only a portion of the medical waste stream is classified as regulated medical waste and is subject to treatment requirements. In accordance with 15A NCAC 13B .1201 (9) regulated medical waste means blood and body fluids in individual containers in volumes greater than 20 mL, microbiological waste, and pathological waste.

The North Carolina Medical Waste Management regulations do not require treatment of non-regulated medical waste, such as sharps, bloody gauze and dressings, bandaids, tubing, and used gloves. These items can be landfilled untreated under North Carolina regulations. There are no EPA or OSHA regulations that prohibit landfill disposal of untreated non-regulated medical waste in North Carolina. If non-regulated medical waste is treated in the unit, the conditions herein must be met.

As provided for in 15A NCAC 13B in 1203(b) this process is approved for the treatment of microbiological waste subject to the conditions herein. Blood and body fluids may also be treated as long as free liquids are discharged into a sanitary sewer.

Please note that microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402 Stock #17-40-508-3.) Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

CONDITIONS TO COMPLY WITH APPROVAL:

1. Prior to initiation of operation of this process notification must be sent to this office, attention Ernest Lawrence.

2. The wastewater/sanitary sewer authority serving the facility where the equipment is installed shall be notified prior to any discharge. All discharges must comply with pretreatment requirements.

3. The system shall be operated consistent with manufacturers' specifications and in such a manner as to assure reliable decontamination of the waste to levels represented by the submitted test data.

4. An operations log indicating operating conditions must be maintained and available for inspection by local health department officials and state environmental and health officers.

5. The treatment of sharps by this process must be accomplished in such a fashion that renders the sharps unrecognizable as to their former function. If this is not achieved, the processed waste will be subject to a packaging requirement, using a puncture-resistance container.

6. Processed wastes must be dewatered to the extent they will pass the paint filter liquids test prior to transportation to a waste disposal facility.

7. Prior to operating a facility, a Solid Waste Permit shall be required in accordance with the Solid Waste Management Rules if off-site waste is to be received.

8. This approval does not relieve an owner/operator of this process from obtaining other federal, state, or local permits as necessary.

This letter does not constitute approval to treat pathological waste. Existing treatments for these wastes are readily available and meet the state goals regarding waste management.

This approval and conditions herein are valid until such time as it has been determined that the technology for this treatment no longer meets the requirements of the rules regarding the regulation and treatment of medical waste.

If you have questions please call the Section at 919-733-0692.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc Ernest Lawrence

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary

DEHNR

October 12, 1993

Dr. Frederick T. Marin
Medifor-X Corporation
21 Ridgewood Drive
Redding, CT 06896

Dear Dr. Marin:

This is in response to your request for approval of the Medifor-X Dispoz-All 2000 as an alternative method for treating medical waste.

Only a portion of the medical waste stream is classified as regulated medical waste and is subject to treatment requirements. In accordance with 15A NCAC 13B .1201 (9) regulated medical waste means blood and body fluids in individual containers in volumes greater than 20 mL, microbiological waste, and pathological waste.

The North Carolina Medical Waste Management regulations do not require treatment of non-regulated medical waste, such as sharps, bloody gauze and dressings, bandaids, tubing, and used gloves. These items can be landfilled untreated under North Carolina regulations. There are no EPA or OSHA regulations that prohibit landfill disposal of untreated non-regulated medical waste in North Carolina. If non-regulated medical waste is treated in the unit, the conditions herein must be met.

As provided for in 15A NCAC 13B in 1203(b) this process is approved for the treatment of microbiological waste subject to the conditions herein.

Please note that microbiological and biomedical laboratories should follow guidelines of the CDC-NIH ("Biosafety in Microbiological and Biomedical Laboratories", Supt. of Documents, US GPO, Washington, DC 20402 Stock #17-40-508-3.) Note that these guidelines may specify that waste cultures of certain pathogenic species be steam sterilized before removal from the lab.

CONDITIONS TO COMPLY WITH APPROVAL:

1. Prior to initiation of operation of this process notification must be sent to the NC Solid Waste Section.

2. If the system produces liquid discharges, notification of this waste management practice shall be made to the wastewater/sanitary sewer authority serving the facility where the equipment is installed prior to any discharge. All discharges must comply with pretreatment requirements.

3. The system shall be operated consistent with manufacturers' specifications and in such a manner as to assure reliable decontamination of the waste to levels represented by the submitted test data.

4. An operations log indicating operating conditions must be maintained and available for inspection by local health department officials and state environmental and health officers.

5. The treatment of sharps by this process must be accomplished in such a fashion that renders the sharps unrecognizable as to their former function. If this is not achieved, the processed waste will be subject to a packaging requirement, using a puncture-resistance container.

6. Processed wastes must be dewatered to the extent they will pass the paint filter liquids test prior to transportation to a waste disposal facility.

7. Prior to operating a facility, a Solid Waste Permit shall be required in accordance with the Solid Waste Management Rules if off-site waste is to be received.

8. This approval does not relieve an owner/operator of this process from obtaining other federal, state, or local permits as necessary.

This letter does not constitute approval to treat pathological waste or blood and body fluids. Existing treatments for these wastes are readily available and meet the state goals regarding waste management.

This approval and conditions herein are valid until such time as it has been determined that the technology for this treatment no longer meets the requirements of the rules regarding the regulation and treatment of medical waste.

If you have questions please call the Section at 919-733-0692.

Sincerely,

Dexter Matthews, Chief
Solid Waste Section

cc Ernest Lawrence

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary

DEHNR

September 2, 1993

Mr. Charles Solomons, President
SPS Medical Equipment Corporation
450 West First Avenue
Roselle, NJ07203

Dear Mr. Solomons:

This is in response to your letter about the "Needle-Eater" Sharps Disposal System. As stated in the August 9, 1990 letter from this office, the medical waste rules do not require treatment of sharps, but do require that sharps be packaged in a container that is rigid, puncture-resistant, and leak-proof when in an upright position. As long as the unit packages sharps in a container that meets these specifications further approval is not required from this office. Solid waste that does not pass the paint filter test and contains free liquids cannot be disposed with general solid waste.

The Department of Labor should be consulted to determine if there are any OSHA requirements for workplace safety.

If you have any questions please call 919-733-0692.

Sincerely,

Ernest Lawrence, Ph.D.
Environmental Specialist

State of North Carolina
Department of Environment,
Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary

DEHNR

September 15, 1993

Mr. William J. Murphy
OBF Industries, Inc.
2719 Curtiss Street
Downers Grove, Illinois 60515

Dear Mr. Murphy:

This is in response to your application for statewide approval of the product Premisorb 2/Vital 2 for treatment of blood and body fluids. The NC Medical Waste Management Regulations specify incineration and sanitary sewage systems as acceptable means for disposal of blood and body fluids (15A NCAC 13B .1203(a)(1)). The use of Premisorb as a pretreatment step prior to incineration does not require approval by the Division of Solid Waste Management.

Current regulations prohibit North Carolina landfills from receiving liquids. Since the stability of solidified liquids under landfill conditions is unknown, blood and body fluids treated with Premisorb cannot be disposed in North Carolina landfills.

If you have any questions, please feel free to call 919-733-0692.

Sincerely,

Ernest Lawrence

Ernest Lawrence, Ph.D.
Environmental Specialist

Health and Natural Resources
Division of Solid Waste Management

James B. Hunt, Jr., Governor
Jonathan B. Howes, Secretary

DEHNR

September 15, 1993

Mr. Jonathan Bicken
D.O.C.C. Inc.
240 East 76th Street
New York, New York 10021

Dear Mr. Bicken:

The Division of Solid Waste Management is unable to approve the D.O.C.C. Demolyzer medical waste treatment system based on currently submitted information. The submitted test protocols were not adequate to demonstrate efficacy of the unit.

Problems with the submitted test data include:

Omission of test controls
The independent lab stated that the "controls" were counts of the inoculum used to set up the test, and counts of organisms on the inoculated needles and syringes prior to treatment. These cannot be considered test controls, but are before-treatment counts.

An acceptable control would be inoculated waste which is not subjected to the treatment temperature.

No actual counts of organisms inoculated on the waste
Actual before-treatment counts are not given for some items, and the results state "TNTC" meaning "too numerous to count." Correspondence from the independent lab stated that this means >300 cfu/mL, but that the actual count is expected to be close to the counts of the inoculum (10^8 to 10^9).

This data cannot be accepted without actual quantitation. This requires additional dilutions and counts to obtain actual numbers. Assumed numbers are unacceptable.

P.O. Box 27687, Raleigh, North Carolina 27611-7687 Telephone 919-733-4996 FAX 919-733-4810

ther consideration of the system will require submission of additional data. If you have questions please call 919-733-0692.

Thank you for your interest and application. I look forward to working with you further.

Sincerely,

Ernest Lawrence

Ernest Lawrence, Ph.D.
Environmental Specialist