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PERMITTING AND STATE AUTHORIZATION ISSUES

STAATT II also reviewed several of the permitting issues identified in STAATT I, as summarized in the following discussions.

User Verification: Biological Inactivation Efficacy Monitoring

User verification methodology is necessary to periodically verify to the equipment's user and the state that the treatment unit is functioning properly, that proper operating procedures are used, and that performance standards are achieved. User verification protocols will employ biological indicators in addition to available verified parametric monitoring. Protocols used will have previously been approved by the state to assure the protocols are congruent with the treatment method/mechanism.

Specifically, to fulfill treatment efficacy and documentation requirements recommended for user verification, the equipment user must:

- Demonstrate that required resistant bacterial endospores (as recommended in Table 2-2) are inactivated to Level III criteria under standard operating procedures
- Establish a frequency of biological and/or parametric monitoring
- Document and record all biological indicator and parametric monitoring data

Since 1994, verification of compliance appears to be more of a state environmental or department of health issue as well as part of the accrediting process of the Joint Commission on Accreditation of Healthcare Organizations under the Environment of Care Standard (see Selected Bibliography). The Occupational Safety and Health Administration (OSHA) continues to focus on issues of occupational safety. User verification requirements recommended are contained in the "State Guideline for Approval of Alternate Medical Waste Technologies" presented in Appendix A.

Commercial Versus On-Site Facilities

Commercial and on-site facilities (i.e., hospitals) can be typically distinguished by the increased volume of waste throughput from commercial facilities. As such, additional

process controls, treatment efficacy monitoring, and permitting are necessitated to ensure effective treatment is maintained and that environmental and occupational/public health and safety concerns are met. As a facility applying for commercial medical waste treatment status, additional permitting requirements may be imposed under other solid or special waste treatment/disposal regulations. As such, cooperative efforts between permitting agencies or divisions is necessitated to ensure the facility is meeting its environmental health and safety responsibilities. To assist in identifying the potential commercial application of a medical waste treatment technology, the STAATT II participants continued to recommend that the potential use of the technology be indicated in technology review information supplied to the state by the equipment manufacturer.

Additionally, while healthcare facilities with on-site treatment capabilities typically treat only their own waste, some have considered accepting waste from off-site facilities and/or transporters. This practice may require additional oversight by regulatory agencies.

Previously Approved Technologies

While the pace of development of new technologies has slowed somewhat, previously granted approvals are still an issue. However, this appears to have been addressed as was initially recommended by STAATT I.

An option that is used today provides the granting of approval for a technology with the provision that any modification to the equipment would require re-application for approval under current standards. As an example, the State of New York Department of Health in its approval letter continues to include the following statement:

> "This approval is granted for this specific system used in your efficacy studies and should not be construed as a general endorsement of the technology employed or any other unit or system. Any modifications of the system will require separate approval of the department and may involve further efficacy testing."

A second option limits the granted site or use permit to a specific time period (e.g., 3 or 5 years). At the time of renewal, the unit must demonstrate that it meets the efficacy criteria and other permit conditions at the levels prescribed in the new standards.

As a third option, the state could mandate that upon the issuance of the new medical waste treatment efficacy standards, pre-existing equipment subject to regulation would be required to comply with current efficacy standards within a set time period. Following compliance, the user would have the option to replace the existing equipment with approved technology, retrofit the equipment to meet current standards, or take the equipment out of service. Incorporation of additional provisions

as stated in Option One or Option Two with those in Option Three would ensure that technology meeting current standards would remain in compliance with future, more restrictive regulations.

Steam sterilizers or autoclaves are not considered "emerging treatment technology." Steam sterilization process has been used for decades to sterilize medical products, biological products, and medical or biohazardous waste and is generally recognized as a traditional sterilization process. Accordingly, many states still do not consider steam sterilization to be a new technology and do not require any additional approval as such. It is recommended by the STAATT II participants that steam sterilization not be subject to registration and technology approval requirements unless it is to be used for treatment of items such as pathological or chemotherapeutic waste. Site and operation permits, as well as validation and challenge testing, would still be necessitated, as required, under applicable state regulations.

The STAATT I participants, however, did recognize that the steam sterilization process is subject to waste load variables and operator control which could lead to inadequate processing of the waste. To assist in documenting that the process is effective, the equipment operator should:

- Adopt standard written operating procedures which denote the following:
  - Sterilization cycle time, temperature, pressure
  - Types of waste acceptable
  - Types of containers and closures acceptable
  - Loading patterns or quantity limitations
- Document times/temperatures for each complete sterilization cycle
- Use time-temperature sensitive indicators to visually note the waste has been decontaminated
- Use biological indicators placed in the waste load (or simulated load) periodically to verify that conditions are met to achieve decontamination
- Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results

Small Medical Waste Treatment Devices

As stated previously, Level III criteria are applicable to all medical waste treatment devices, including small "counter-top" devices. It was recognized by the STAATT I participants that registration of all small medical waste treatment device users by the authorized state regulatory agency would be a monumental effort. To minimize the state's effort, it is suggested that the equipment's manufacturer (or vendor) take responsibility in fulfilling siting requirements as a condition of technology approval. As such, the manufacturer would provide during the technology approval process, all information required of site approval for a typical site for which the equipment is designed. Information required of the small treatment device manufacturer would be similar to the information required of all medical waste treatment equipment manufacturers, but would include all materials and documents required of the user to ensure proper use, safety, and effective treatment. These materials and documents would include the following:

- An operations and maintenance manual
- Information on proper use and potential misuse
- Treatment efficacy testing instructions
- Training/education manual
- Available service agreements/programs

Upon the installation of the treatment device, the manufacturer would complete a record of the buyer, the location, and the results of on-site challenge testing at the time of purchase. This information could be submitted annually to the state by the manufacturer as the notification record of site registrations of equipment installed that previous year. It is recommended that small medical waste treatment devices be specifically identified upon initial application for technology approval.

Waste Residue Disposal

The disposition of waste residues remains an environmental concern in certain parts of the United States. To ensure that waste residues are properly identified and disposed of, the participants continue to recommend that they be addressed at both the technology approval stage and equipment siting stage of the review process. During the technology approval process, information on the characteristic(s) of the waste residues, the mechanism(s), and the mode(s) of their disposal should be provided by the manufacturer. This information should include the following:

- A description of residues (i.e., liquid, solid, shredded, hazardous constituents)

- Waste designation (i.e. hazardous, special, general)
- Disposal mechanisms (i.e. landfilling, incineration, recycling)
- Recycling efforts, if anticipated, (i.e., waste types, amounts, percentages, name and location of recycling effort)

During the siting stage of the review process, specific information on residue disposal should also be required. This information should include all of the above information, but specifically state with attached documentation the actual mechanism and location of disposal. To avoid recycling being used as a mechanism to potentially avoid regulatory permitting requirements and to assure that recycling efforts are legitimate, the state should request the following information from the on-site or commercial facility:

- The types of waste residue to be recycled
- The amounts of waste residue to be recycled
- The percentage of the total waste and waste residue to be recycled
- The recycling mechanism used
- The location of the recycler

Previously untreated medical wastes used in the development and testing of prototypical equipment should continue to be considered as potentially infectious and as such, be disposed of as untreated medical waste. To minimize environmental and occupational exposures that may result from using untreated medical wastes, it was recommended that prototypical equipment be tested using non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed of as general solid wastes after verification of treatment effectiveness.

It was the consensus of the STAATT II participants that "treated" waste need not be monitored for microorganisms. The most appropriate method for evaluating the efficacy of treatment systems is either through the use of biological indicators as has already been discussed in Chapter 2 or parametric monitoring that has been correlated with acceptable levels of microbial inactivation. As has been discussed in previous meetings, the use of the terms sterilization and disinfection are not as easily applied to the treatment of medical waste as they are to medical devices. Medical waste treatment systems should achieve an acceptable level of microbial inactivation (for example, a consistent reduction in the concentration of viable microorganisms). Low levels of microorganisms which may be found in treated waste are not likely to constitute a danger to the public's health and safety. Furthermore, the treated waste would

routinely be taken to a sanitary landfill for disposal. The conditions within such a landfill are not conducive to the growth of most human pathogens. Given all of these factors, the participants agreed that treated medical waste need not be tested for the presence of viable microorganisms.

Operator training

Affecting both treatment efficacy and operator safety, mandated operator training is recommended (as appropriate: small treatment devices may be excluded from this recommendation) as a requirement for process approval. To assure proper operation of the treatment process, the manufacturer would be requested to provide an operator training program which would include:

- Training and education materials adequately describing the process, process monitors and safety controls
- Contingency plans in the event of abnormal occurrences (i.e., power failure, jamming, inadequate chemical concentrations) and emergencies (i.e., fire, explosion, release of chemical or biohazardous materials)
- Personal protective equipment requirements
- A listing of all potential occupational safety and health risks posed by the equipment and its use

The proposed "ASME Standard for the Qualification and Certification of Medical Waste Incinerator Operators" (September 1992) was reviewed for its potential applicability as a guideline for developing required elements for operator training. Although the participants agreed that the proposed standard was far too extensive for emerging medical waste treatment equipment operations, certain components might provide the basis for an operator training program for other medical waste treatment technologies.

Equipment Operations Plan

The proposed "ASME Standard for the Qualification and Certification of Medical Waste Incinerator Operators" (September 1992) offers elements for inclusion into an equipment operations plan. Using this proposed standard as a guide, the following components are recommended for incorporation into an equipment operations plan:

- A description of all mechanical equipment, instrumentation, and power controls
- A description of systems' operations including waste types acceptable, loading parameters, process monitors, treatment conditions, and disposal

- A description of all parametric controls and monitoring devices, their appropriate settings, and established ranges and operating parameters as correlated with biological indicators, and calibration requirements
- A description of the methods required to ensure process monitoring instrumentation is operating properly
- A description of methods and schedules for periodic calibration of process monitoring instrumentation
- A description of proper mechanical and equipment responses, including identification of system upsets (such as power failure, jamming, inadequate treatment conditions) and emergency conditions (for example, fire, explosion, release of chemical or biohazardous materials)
- A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- A description of all potential occupational safety and health risks posed by the equipment and its use
- Assignment of the following responsibilities to specific persons:
  - Collecting and organizing data for inclusion into the operating record
  - Evaluating any discrepancies or problems
  - Recommending actions to correct identified problems
  - Evaluating actions taken and documenting improvement

Emergency and Contingency Response Plan

The development of a separate plan was recommended by the participants to assist the operating facility in properly responding to an unplanned, emergency, or abnormal event. The primary objectives of this emergency and contingency response plan are:

- To prevent or minimize biological and/or chemical agent release to the environment
- To prevent or minimize exposure to the equipment operator or other support or maintenance personnel
- To develop contingency medical waste treatment or disposal alternatives for untreated or inadequately treated waste

The plan should take into consideration those events that result in:

- Failure in the treatment technology (such as inadequate chemical concentration, temperature)
- Mechanical failure (such as a jammed shredder, inadequate steam pressure)
- Equipment shut-down in mid-cycle
- Spill or release of biological or chemical agents
- Accumulation of untreated or inadequately treated medical waste

The development of the plan will by necessity, be a shared responsibility between the manufacturer (vendor) and the equipment's user. As the equipment designer, the manufacturer (vendor) should provide evidence of a failure mode and effect analysis to prevent or minimize inadequate treatment or biological/chemical exposures through process design, process control, and process monitoring. The results of this analysis should be provided through:

- A description of all process controls and process monitoring devices, their appropriate settings, and established ranges and operating parameters (for example, DOP testing of HEPA filters, see Selected Bibliography)
- A description of all parametric controls and associated monitoring devices, their appropriate settings, and established ranges and operating parameters as correlated with biological indicators, and calibration requirements
- A description of proper mechanical and equipment responses, including identification of system upsets or malfunction (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials)
- A description of the methods required to ensure process and parametric monitoring devices are operating properly
- A description of methods and schedules for periodic calibration of process and parametric control and monitoring instrumentation
- A description of equipment/inadequately treated waste decontamination procedures required in the event of a mid-cycle shut-down

The equipment's user has the responsibility of incorporating the manufacturer supplied information into a descriptive written emergency and contingency response plan. Additional information to be provided within the plan should include:

- A description of all potential occupational safety and health risks posed by the equipment and its use
- A description of proper responses for system upsets and emergency conditions
- A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- A description of proper medical response if required
- A pre-designated disposal site for untreated or inadequately treated medical waste if a mechanical failure precludes the treatment equipment's use

There are some additional items for regulators as well as vendors to be aware of regarding safety of employees. The information comes from a two year study conducted by NIOSH to evaluate biological and chemical exposures in medical waste treatment facilities. These considerations would apply to anyone using any type of treatment device (small or large, on-site or commercial facility).

Recommendations from NIOSH Report (See Selected Bibliography)

- Perform periodic general safety inspections including checks based on OSHA regulations and other applicable codes. Particular emphasis should be placed on adherence to the electrical code.
- Regularly calibrate and check functioning of testing equipment including battery checks.
- Continue providing regular worker training.
- Do not allow workers to enter the treatment equipment unless absolutely necessary. Explore other options first such as the use of a long handled broom to clean the ventilation screen in the microwave unit. If necessary, make provision for sanitization of the waste and work systems before the worker enters and require the use of protective clothing, gloves, boots, and head protection.
- Provide protective equipment as appropriate to the facility including adequate splash protection.
- Require that protective clothing that was worn in the facility not be worn home. This stricture should include all outerwear.
- Reduce possible transfer of contamination from the waste treatment areas to other areas by having shoes that were worn in the plant changed or covered before the wearer enters an office area.

- Give careful attention to daily routine cleaning and decontamination of treatment units and other facility surfaces.
- Provide areas separate from the medical waste treatment for workers to use for taking breaks and eating lunch.
- Carefully follow and upgrade worker protection programs to include specific glove use protocols based on the situation in each facility and the NIOSH recommendations for glove usage. Suggestions to consider include double gloving where one glove is likely to rip, wearing work gloves over disposable gloves when needed, and consistently using gloves when operating controls.
- Monitor noise levels periodically and require that hearing protection be worn in high noise areas and in any areas specified in hearing protection programs.
- Reconsider waste packaging and handling procedures to minimize worker exposure.
- For future installations or major upgrades, ensure that process design engineers consider the worker-facility-unit interfaces to design out hazards.

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RESEARCH AND DEVELOPMENT

STAATT I raised the issue of state responsibility and regulation in the research and developmental phase of medical waste technologies. It was recognized in 1994 that there was a need to develop new technologies, but time, staffing and funding of the permitting state agency might preclude the state's involvement in a research and development project. Concerns raised in state involvement with research and development projects included the following:

- Process of establishing research and development variances, including limitations and allowances
- Knowledge of and permitting of potential environmental emissions and safety considerations
- Treatment process residue disposal
- Agency funding and staffing

The approach suggested by STAATT I in 1994 (language from the State of Illinois Environmental Protection Agency (IEPA) for "experimental permits") is still valid today. IEPA required "applicants to provide proof that the process or technique has a reasonable chance for success. Additionally the IEPA required evidence that "environmental hazards are minimal" and a "description of the type of residuals anticipated and how they will be managed and disposed." As proposed, the experimental permits were to be granted for two years with a one-time renewal based on submittal of application of renewal and a report summarizing equipment performance, treatment efficacy results, and management of residual materials.

It was noted that IEPA stated that the "Agency may issue experimental permits" allowing the IEPA discretion in granting an experimental permit. To minimize concerns that research and development of a medical waste treatment technology may pose environmental and occupation risks, an application form similar to that required of a technology seeking formal approval might be submitted. The form would request available environmental and occupational safety data in addition to equipment specifications, residue management and disposal, and any available preliminary treatment efficacy data and protocols.

To further minimize environmental and occupational safety concerns that might arise during research and development, it was recommended that the prototypical equipment be tested using non-infectious or previously treated medical waste (i.e., treated by an approved process such steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed as general solid wastes upon verification of treatment effectiveness. Non-treated medical wastes used during research and development would require agency-approved treatment after testing.

The following statements can be adapted into guidance document language:

- Research and development permits are to be granted for a period of two years with a one-time renewal
- Granting of a research and development permit does not assure future site approval at that site upon state approval of the process
- Research and development permitted facilities cannot accept waste for monetary gain
- Research and development permitted facilities must have any experimentally treated medical waste treated by a state approved medical waste treatment process before disposal or recycling

Funding of the additional costs incurred by the state as a result of the increased oversight activities associated with a research and development project can be addressed by some mechanism (such as a set fee for time and materials) established to reimburse the state for these activities.

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RECOMMENDATIONS FOR FUTURE ACTIVITIES

The updating of the original STAATT document fulfills one of the recommendations made in 1994 for future activities. Efforts continue moving towards a nationally recognized foundation for the review and approval of emerging medical waste treatment technologies. The American Society for Testing Materials (ASTM) and Underwriters Laboratories (UL) have expressed interest in using the STAATT report in the development of nationally recognized standards for the evaluation of medical waste treatment technologies. Data is also now available on the potential release of biological aerosols from alternative medical waste treatment equipment (See Selected Bibliography—NIOSH Report). To continue with the further development and implementation of a nationally recognized guideline, the participants continue to recommend:

- The establishment of criteria and procedures for emergency and contingency response to ensure adequate equipment decontamination and operator safety in the event of a mid-cycle shut-down or other abnormal occurrence
- The further enhancement of the present clearinghouse to create a network for the following:
  - Future regulatory activities
  - Integration of technology approvals/denials
  - Information on equipment failures
  - Development of emergency equipment decontamination protocols
  - Provision of access to technical expertise and documentation
  - Assistance to manufacturers in the approval process
  - Protocol review/assessment/development/continuity
- Continued committee discussion and interaction with the USEPA Office of Pesticide Programs as that office further develops its registration requirements and protocols for medical waste treatment technologies using chemical agents

- The expanded integration of health and safety oversight of medical waste treatment activities by state regulatory agencies and professional accrediting associations to include defined oversight responsibilities and inspector training programs

As was discussed in the introduction, this STAATT guidance document is not a static work but will continue to change as the importance of medical waste is more widely recognized. It may be expected that additional STAATT conferences and revisions of this document will occur in the future.

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GLOSSARY

"AOAC" refers to the Association of Official Analytical Chemists.

"ATCC" refers to the American Type Culture Collection.

"Biological Indicator(s)" means those microorganisms that are used as representative microbial agents in medical waste treatment efficacy studies and testing.

"cfu" refers to colony forming units.

"Challenge Load" means a medical waste load that has been constructed by composition (i.e., organic content, density, moisture/liquid content, or other physical or chemical composition) or amount to provide an appropriate challenge to treatment effectiveness of the treatment process and microbial inactivating agent.

"Challenge Testing" means microbiological testing conducted periodically on a medical waste treatment technology. Frequency of testing varies according to state statutes and regulations (e.g., weekly, monthly, every 6 months).

"Emerging Alternate Medical Waste Treatment Technology" means any medical waste treatment technology other than incineration and steam sterilization (autoclaving).

"FIFRA" refers to the Federal Insecticide, Fungicide, and Rodenticide Act.

"Log_{10} kill" is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment.

"4 Log_{10} Reduction" is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population; i.e., a 99.99% reduction.

"6 Log_{10} Reduction" is defined as a 6 decade reduction or a 0.000001 survival probability in a microbial population; i.e., a 99.9999% reduction.

"Participants" refers to the State and Territorial Association on Alternate Treatment Technologies.

"Pathogen Surrogate(s)" means those microorganisms that are used as biological indicators in medical waste treatment efficacy studies and testing that represent known microbial pathogens.

"STAATT I" means the State and Territorial Association on Alternative Treatment Technologies guidance document developed as a result of meeting held between 1992 and 1994.

"STAATT II" means the State and Territorial Association on Alternative Treatment Technologies meeting held in New Orleans in the month of February, 1998 to update STAATT I.

"Surrogate Load" means a waste load that has been constructed to represent a typical medical waste load by composition (i.e., organic content, density, moisture or liquid content, or other physical or chemical composition) and amount.

"Validation Testing" means microbiological testing conducted at the time of installation of a medical waste treatment technology.

A

STATE GUIDELINES FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

Preface

This guideline summarizes the discussions and results of the State and Territorial Association on Alternate Treatment Technologies. It should be emphasized that the recommendations provided by the association and adopted by the participating states are an attempt to find commonalty on many of the issues and criteria required in the medical waste treatment technology review process. Recognizing that all states may not totally agree with these recommended criteria or protocols, this guideline continues to serve as a model for the development of state guidelines or regulations. It is also recognized that definitions, terms, and regulatory methodologies used within the framework of this guideline may not be compatible with granted legislative authority or existing regulatory language. As such, this guideline may periodically require revision to conform with specific state statutes and regulatory requirements.

A. Definition of Microbial Inactivation

A1. Inactivation is required to be demonstrated of vegetative bacteria, fungi, lipid/non-lipid viruses, parasites, and/or mycobacteria at a 6 Log_{10} reduction or greater; a 6 Log_{10} reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction).

A2. Inactivation is required to be demonstrated of *B. stearothermophilus* spores or *B. subtilis* spores at a 4 Log_{10} reduction or greater; a 4 Log_{10} reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction).

B. Representative of Biological Indicators

B1. One or more representative microorganisms from each microbial group may be used in treatment efficacy evaluation.

- a) Vegetative Bacteria
  Staphylococcus aureus (ATCC 6538)
  Pseudomonas aeruginosa (ATCC 15442)

- b) Fungi
  Candida albicans (ATCC 18804)
  Penicillium chrysogenum (ATCC 24791)
  Aspergillus niger

- c) Viruses
  Polio 2 or Polio 3
  MS-2 Bacteriophage (ATCC 15597-B1)

- d) Parasites
  Cryptosporidium spp. Oocysts
  Giardia spp. cysts

- e) Mycobacteria
  Mycobacterium terrae
  *Mycobacterium phlei**
  Mycobacterium bovis (BCG) (ATCC 35743)*

B2. Spores from one of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems.

- a) *Bacillus stearothermophilus* (ATCC 7953)*

- b) *Bacillus subtilis* (ATCC 19659)*

* At a minimum, alternative treatment technologies shall tests for these microorganisms.

C. Quantification of Microbial Inactivation

C1. Microbial inactivation ("kill") efficacy is equated to "Log_{10} kill" which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment. This definition is equated as:

Log_{10} kill = Log_{10}(cfu/g "I") -Log_{10}(cfu/g "R")

where:

Log_{10} kill is equivalent to the term Log_{10} reduction.
"I" is the number of viable test microorganisms introduced into the treatment unit.

"R" is the number of viable test microorganisms recovered after treatment.
"cfu/g" are colony forming units per gram of waste solids.

C2. For those treatment processes that can maintain the integrity of the biological indicator carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, biological indicators of the required strain and concentration can be used to demonstrate treatment efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator.

C3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation/grinding), quantitative measurement of treatment efficacy requires a two step approach: Step 1, "Control"; Step 2, "Test." The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

- a) Step 1:

  1. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.

  2. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the microbial inactivation agent (i.e., heat, chemicals).

  3. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

  4. Plate recovered microorganism suspensions to quantify microbial recovery. (The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the microbial inactivation agent).

  5. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction as specified in Section A (i.e., a 6 Log_{10} reduction for vegetative microorganisms or a 4 Log_{10} reduction for bacterial spores). This can be defined by the following equations:

     $Log_{10}RC = Log_{10}IC - Log_{10}NR$

     or

     $Log_{10}NR = Log_{10}IC - Log_{10}RC$

where: $Log_{10}RC > 6$ for vegetative microorganisms and > 4 for bacterial spores and where: $Log_{10}RC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) recovered in the non-treated processed waste residue.

$Log_{10}IC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit.

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) which were not recovered after processing. $Log_{10}NR$ represents an accountability factor for microbial loss.

- b) Step 2:

1. Use microbial cultures of the same concentration as in Step 1.
2. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the microbial inactivation agent.
3. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
4. Plate recovered microorganism suspensions to quantify microbial recovery.
5. From data collected from Step 1 and Step 2, the level of microbial inactivation (i.e., "Log_{10} kill") is calculated by employing the following equation:

Log_{10} kill = $Log_{10}IT - Log_{10}NR - Log_{10}RT$, where:

Log_{10} kill is equivalent to the term Log_{10} reduction.

$Log_{10}IT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit. $Log_{10}IT = Log_{10}IC$.

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) which were not recovered after processing.

$Log_{10}RT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) recovered in treated processed waste residue.

D. Efficacy Testing Protocols

D1. Methodology employed to determine treatment efficacy of the technology will need to assure required microbial inactivation and assure the protocols are congruent with the treatment method. Protocols developed for efficacy testing shall incorporate, as applicable, recognized standard procedures such as those found in Test Methods for Evaluating Solid Waste, Physical/Chemical Methods and Standard Methods for the Examination of Water and Waste Water.

D2. The Agency shall prescribe those types and compositions of medical wastes that present the most challenge to treatment effectiveness under normal operating conditions of the equipment reviewed.

D3. Dependent on the treatment process and treatment efficacy mechanisms utilized, protocols evaluating medical waste treatment systems shall specifically delineate or incorporate, as applicable:

- a) Waste compositions that typify actual waste to be processed
- b) Waste types that provide a challenge to the treatment process
- c) Comparable conditions to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load density, load volume)
- d) Assurances that biological indicators (i.e., ampules, strips) are not artificially affected by the treatment process
- e) Assurances of inoculum traceability, purity, viability and concentration
- f) Dilution and neutralization methods that do not affect microorganism viability
- g) Microorganism recovery methodologies that are statistically correct (i.e., sample collection, number of samples/test, number of colony forming units/plate)
- h) Appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times)

E. Technology Approval Process

E1. To initiate the technology review process the manufacturer (vendor) shall complete and submit the following information:

- a) Provide a detailed description of the medical waste treatment equipment to be tested including manufacturer's instructions and equipment specifications,

operating procedures and conditions including, as applicable, treatment times, pressure, temperatures, chemical concentrations, irradiation doses, feed rates, and waste load composition

- b) Provide documentation demonstrating the treatment method meets microbial inactivation criteria and required testing protocols including a detailed description of the test procedures and calculations used in fulfilling required performance standards verifying treatment efficacy, of user verification methodology, and of microbial culturing protocols which ensure traceability, purity and concentration
- c) Provide information on available parametric controls/monitoring devices, verifying treatment efficacy and ensuring operator non-interference
- d) Provide documentation of applicable emission controls for suspected emissions
- e) Provide information relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling
- f) Provide documentation providing occupational safety and health assurance
- g) Provide information on energy efficiency and other potential benefits the treatment technology has to offer to the environment

E2. The manufacturer (vendor) shall demonstrate that all required pathogen surrogates and resistant bacterial endospores are inactivated to criteria specified in Section A and Section C under all Agency specified challenge waste load compositions.

E3. The manufacturer (vendor) shall develop and demonstrate that site approval and user verification testing protocols are workable and valid.

E4. The manufacturer (vendor) shall demonstrate where technically practical, the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

E5. The manufacturer (vendor) shall develop contingency response plans and protocols for use in the event of an emergency, accident, or equipment malfunction. The manufacturer (vendor) shall demonstrate that developed protocols are effective in providing operator safety from physical, chemical, or biological exposures during and after the event including decontamination procedures.

E6. The manufacturer (vendor) shall demonstrate evidence of U.S. EPA pesticide registration for those treatment processes that employ a chemical agent to inactivate microorganisms.

E7. Upon demonstration to the Agency's satisfaction, technology approval granted is granted only under the conditions specified in the manufacturer's instructions and equipment specifications, operating procedures and conditions including, as applicable, treatment times, temperatures, pressure, chemical concentrations, irradiation doses, feed rates, and waste load composition. Any significant revisions to these equipment and operating conditions, as warranted relevant to the Agency, will require re-application for approval to the Agency.

F. Site Approval Process

F1. To fulfill treatment efficacy and information requirements for site approval, the equipment user shall:

- a) Demonstrate that the equipment sited is the same equipment and process approved by the Agency as specified in Section E
- b) Demonstrate that required resistant bacterial endospores are inactivated as specified in Section A2 criteria under typical waste load and Agency specified challenge compositions
- c) Verify that user verification protocols adequately demonstrate treatment effectiveness
- d) Verify the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment

F2. The site facility shall provide a written operations plan that includes:

- a) The names or positions of the equipment operators
- b) The waste types or categories to be treated
- c) Waste segregation procedures required
- d) Wastes types prohibited for treatment
- e) Equipment operation parameters
- f) Treatment efficacy monitoring procedures
- g) Personal protective equipment requirements
- h) Operator training requirements

F3. The site facility shall provide a written emergency and contingency response plan that includes:

- a) A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials)
- b) A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- c) A description of all potential occupational safety and health risks posed by the equipment and its use

F4. The site facility shall submit to the Agency for their review:

- a) Equipment model number and serial number
- b) Equipment specification and operations manual
- c) A copy of the facility's operations plan
- d) A copy of the facility's emergency and contingency response plan
- e) Certification documentation of operator training

F5. As a condition of site approval, the Agency shall have a right to inspect the facility and the right to revoke site approval if health and safety violations are discovered, if permit conditions are not being fulfilled, or if the facility is not adhering to its written plans.

F6. Any modifications to the medical waste treatment unit may require re-approval by the Agency and may involve further efficacy testing.

G. User Verification

G1. To verify that the medical waste treatment unit is functioning properly and that performance standards are achieved, the equipment user shall:

- a) Demonstrate that required resistant bacterial endospores are inactivated to criteria as specified in Section A2 under standard operating procedures using protocols that have previously been approved by the Agency as specified under Section E and F
- b) Establish a frequency of biological monitoring

- c) Document and record all biological indicator and parametric monitoring data

G2. To document treatment efficacy for steam sterilizers and autoclaves, the equipment operator shall:

- a) Adopt standard written operating procedures which denote:
  - 1) Sterilization cycle time, temperature, pressure
  - 2) Types of waste acceptable
  - 3) Types of containers and closures acceptable
  - 4) Loading patterns or quantity limitations
- b) Document times/temperatures for each complete sterilization cycle
- c) Use time-temperature sensitive indicators to visually denote the waste has been decontaminated
- d) Use biological indicators placed in the waste load (or simulated load) periodically to verify conditions meet microbial inactivation requirements as specified in Section A2
- e) Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results

G3. Medical waste incinerators are to be operated, maintained, and monitored as specified in applicable site and operating permits.

H. Small Medical Waste Treatment Devices

H1. All small medical waste treatment devices shall fulfill the requirements necessary for technology approval and shall meet the treatment efficacy requirements as defined in Section A.

H2. Technology and siting approval are the responsibility of the manufacturer or equipment vendor. The manufacturer (vendor) shall provide to the Agency:

- a) All information required for technology approval as defined in Section E
- b) All information required of site approval for a typical site for which the equipment is designed as defined in Section F

- c) All materials and documents required of the user to ensure proper use, safety, and effective treatment

  These materials and documents would include:

  — 1) An operations and maintenance manual

  — 2) Information on proper use and potential misuse

  — 3) Treatment efficacy testing instructions

  — 4) Training/education manual

  — 5) Available service agreements/programs

H3. The manufacturer (vendor) shall furnish the user of the treatment device:

- a) An operations and maintenance manual
- b) Information on proper use and potential misuse
- c) Treatment efficacy testing instructions
- d) Training/education manual
- e) Available service agreements/programs

H4. Upon the installation of the treatment device, the manufacturer shall compile a record of the buyer, the location, and the results of onsite challenge testing at time of purchase. This information shall be submitted annually to the Agency by the manufacturer (vendor) as the notification record of site registrations of equipment installed that previous year.

I. Previously Approved Technologies

I1. Medical waste treatment equipment which is subject to these registration and technology approval requirements that has been installed and operated before January 1, 1998, shall comply with current efficacy standards by (date). By (date), pre-existing medical waste treatment equipment shall have been modified to meet current standards, taken out of service, or replaced by approved equipment.

I2. Steam sterilizers, autoclaves, and incinerators are not included within the category of "emerging treatment technologies" and are not subject to these registration and technology approval requirements. Site and operation permits are still necessitated, as required, under applicable state regulations.

J. Waste Residue Disposal

J1. Information on the characteristic(s) of all waste residues (liquids and solids), and the mechanism(s) and mode(s) of their disposal shall be provided by the manufacturer on the "Evaluation of Medical Waste Treatment Technology: Information Request Form." This information will include:

- a) Description of residues (i.e., liquid, solid, shredded, hazardous constituents)
- b) Waste designation (i.e. hazardous, special, general)
- c) Disposal mechanism (i.e. landfilling, incineration, recycling)
- d) Recycling efforts, if anticipated, (i.e., waste types, amounts, percentages, name and location of recycling effort)

J2. Information on waste residue disposal shall be provided by the user facility as required under site approval (Section F). This information shall include:

- a) All information requested in Section J1
- b) The site of disposal (name and address)
- c) The mechanism of disposal (i.e. landfilling or incineration)
- d) The amounts of residue(s) anticipated to be disposed (e.g., volume and weight per week)

J3. If residue(s) are to be recycled the following information shall be provided by the user facility as required under site approval (Section F). This information shall include:

- a) The types of waste residue to be recycled
- b) The amounts of waste residue to be recycled
- c) The percentage of the total waste and waste residue to be recycled
- d) The recycling mechanism used
- e) The name and location of the recycler

J4. Previously untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed as untreated medical waste.

J5. Prototypical equipment testing using non-infectious or previously treated medical waste (i.e., treated by an approved process such steam sterilization) that has been inoculated with recommended pathogen surrogates can be disposed as general solid waste after verification of treatment effectiveness.

J6. All liquid and solid waste residues will be disposed of in accordance with applicable state and local regulations.

K. Operator Training

K1. To assure proper operation of the treatment process, the manufacturer (vendor) shall provide to the user as part of the treatment equipment purchase an operator training program which will include:

- a) A description of all mechanical equipment, instrumentation, and power controls
- b) A description of system's operations including waste types acceptable, loading parameters, process monitors, treatment conditions, and disposal
- c) A description of all parametric controls and monitoring devices, their appropriate settings as correlated with biological indicators, and calibration requirements
- d) A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials)
- e) A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- f) A description of all potential occupational safety and health risks posed by the equipment and its use

K2. The facility shall develop a written equipment operations plan which will include:

- a) Responsibility delegation for safe and effective equipment operation to operating personnel
- b) A description of operating parameters that must be monitored to ensure effective treatment
- c) A description of all process monitoring instrumentation and established ranges for all operating parameters

- d) A description of the methods required to ensure process monitoring instrumentation is operating properly
- e) A description of methods and schedules for periodic calibration of process monitoring instrumentation

K3. The facility shall develop a written contingency and emergency response plan to include:

- a) A description of all potential occupational safety and health risks posed by the equipment and its use
- b) A description of proper responses for system upsets and emergency conditions
- c) A description of personal protective equipment requirements for routine, abnormal, and emergency operations
- d) A description of proper medical response if required
- e) A pre-designated disposal site for untreated or inadequately medical treated waste if a mechanical failure precludes the treatment equipment's use

K4. The facility shall document and keep on record copies of all training for at least 3 years.

L. Research and Development

L1. The Agency may issue an Experimental Permit for medical waste treatment processes or techniques that are undergoing research and development if the applicant can provide evidence that:

- a) Environmental impact is minimal
- b) Occupational exposures are minimal

L2. The Agency's "Evaluation of Medical Waste Treatment Technology: Information Request Form" shall be submitted and shall contain environmental and occupational safety data in addition to equipment specifications, residue management and disposal, and any available preliminary treatment efficacy data and protocols.

L3. All equipment testing shall preferably use non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates listed in Section B. Waste residues generated can be disposed as general solid wastes upon verification of

treatment effectiveness. Untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed as untreated medical waste.

L4. All Experimental Permits have a duration not to exceed two years with a one-time renewal.

L5. Granting of an Experimental Permit does not assure future site approval upon state approval of the process.

L6. Facilities with experimental permits cannot accept waste for monetary gain.

B

TREATMENT EFFICACY TESTING PROTOCOL FOR A GRINDER/CHEMICAL MEDICAL WASTE INACTIVATION PROCESS

I. Materials

A. *Bacillus stearothermophilus* spores as a suspension of 2×10^{10} initial inoculum. [*B. stearothermophilus* spores were chosen as the spore of choice due to the thermophilic nature of *B. stearothermophilus* and its ability to optimally grow at elevated temperatures. Culturing collected waste samples at 60°C using *B. stearothermophilus* spores as a biological indicator reduces the number of potential cross contaminants that might arise on a culture plate. A spore suspension of 2×10^{10} initial inoculum was chosen to provide an adequate number of recoverable spores for determining a 4 Log_{10} reduction. Determination of this concentration may require trial runs to ascertain the recovery concentrations.]

B. Surrogate waste load to be constructed to contain by weight: 5% organic material and 95% plastics, cellulose, and glass. Total weight of sample to be between 15 and 20 pounds. [The surrogate waste load used in this example was constructed to represent the typical medical waste composition that would be treated by this system at the user site location. Surrogate waste loads may also be constructed to replicate medical waste loads which challenge the treatment efficacy of the system. The sample weight of the load was selected as being representative of the feed rate and typical loading conditions of the unit. Weight loads should be constructed to mimic conditions of actual use.]

II. Protocols

A. Control Run

1. Add 2×10^{10} *B. stearothermophilus* spore suspension to surrogate waste load. [The spore suspension should be added as to not expose the researcher or equipment operator to the biological indicator. To minimize potential exposures and to

adequately disperse the spore suspension throughout the load, the spore suspension could be transferred into four or more separate plastic screw-capped tubes. These tubes could subsequently be equally dispersed throughout the surrogate waste load.]

2. Load inoculated surrogate waste into the previously cleaned (decontaminated) treatment unit and run unit without chemical inactivation agent. [The unit should be previously decontaminated to minimize cross contamination from spores originating from previous efficacy testing.]

3. Collect ten 1-gram samples during the duration of the run (i.e., collect samples at the beginning of waste discharge through final discharge). [The amount, number and collection frequency of sample collection will be determined previously by trial runs. The important consideration for this determination is to ensure that during the span of the run, the test data collected provide an accurate reflection of treatment efficacy for the entire load.]

4. Place the 1-gram samples immediately upon collection into pre-weighed (combination weight of both liquid and tube) plastic screw cap tubes containing an appropriate neutralizing solution and vortex vigorously for 5 minutes. [This step is required to neutralize chemical agent activity at the time the waste exits the unit and is necessary to determine actual treatment efficacy during the treatment process and minimize the inclusion of residual chemical activity that might be present. The amount, concentration, and exposure time of the selected neutralizing agent must be pre-determined so as to neutralize the specific chemical agent without inhibiting growth of the biological indicator. Collection tubes are pre-weighed, including neutralizing agent, to determine the weight of the actual waste sample collected.]

5. Construct an approximate 10-gram composite sample from the 10 representative samples collected in Step 3. [This step provides for the evaluation of treatment efficacy of the entire load without assaying each individual sample taken above.]

6. Decant, sieve, and filter as required to separate solid waste material from the neutralizing liquid. Save liquid effluent. [This step is required to wash bacterial spores from the collected waste sample. Protocols involved in this rinsing step will be determined by trial runs to ascertain the best mechanisms to adequately rinse and separate the solid waste components from the liquid rinse.]

7. Wash and vortex solid materials a second time with neutralizing buffer. Decant, sieve, and filter as required to separate solid waste material from liquid. Combine liquid effluent with that obtained in Step 6. [This step provides an extra wash to collect from the waste as many of the spores as possible.]

8. Filter liquid through Millipore™ filtration unit or equivalent to concentrate retrieved spores on membrane filter. Wash filter with 10 mls of citrate or other appropriate

buffer. [This step concentrates retrieved spores to equal the number of spores from 10 grams waste/10 mls buffer or by factoring, the number of spores from 1 gram waste per 1 ml buffer. For example, plating one ml of the liquid would result in the number of cfu's on the plate to be equal to the number spores per one gram of waste.]

- a) Triplicate plate 0.1 ml from the 10 ml concentrate in Step 8 above; this dilution represents Plate A. [This step equates to a total dilution of 1:10.]

- b) Add 1.0 ml of the 10 ml concentrate in Step 8 above to 9.0 mls of buffer solution (this represents a 1:10 serial dilution and is represented as Dilution Tube B). Triplicate plate 0.1 ml of Dilution Tube B; this dilution represents Plate B. [This step equates to a total dilution of 1:100.]

- c) Add 1.0 ml of Dilution Tube B above to 9.0 mls of buffer solution (this represents an additional 1:10 serial dilution and is represented as Dilution Tube C). Triplicate plate 0.1 ml of Dilution Tube C; this dilution represents Plate C. [This step equates to a total dilution of 1:1000).

- d) Add 1.0 ml of Dilution Tube C above to 9.0 mls of buffer solution (this represents an additional 1:10 serial dilution and is represented as Dilution Tube D). Triplicate plate 0.1 ml of Dilution Tube D; this dilution represents Plate D. [This step equates to a total dilution of 1:10,000).

B. Test Run

1. Follow protocols in II A, except run the treatment unit with specified chemical inactivation agent concentrations.

2. Upon washing the membrane filter in Step II. 8 with 10 mls of buffer.

- a) Triplicate plate 1 ml of buffer in Step 2 above via the pour plate method (i.e., 1 ml of spore concentrate into 10-12 mls of liquid agar. Vortex and pour into plate; this represents Plate A'. [This step equates to no dilution factor, i.e., this number represents the number of spores per gram of waste.]

- b) Triplicate plate 0.1 ml of buffer in Step 2 above via the pour plate method (i.e., 0.1 ml of spore concentrate into 10-12 mls of liquid agar. Vortex and pour into plate; this represents Plate B'. [This step equates to a 1:10 dilution factor.]

- c) Add 1.0 ml of the buffer in Step 2 above to 9.0 mls of buffer solution (this represents a 1:10 serial dilution and is represented as Dilution Tube C'). Triplicate plate 0.1 ml of Dilution Tube C'; this dilution represents Plate C'. [This step equates to a total dilution of 1:100.]

III. Calculations

Using the equations found in Section C3 of "State Guideline for Approval of Alternate Medical Waste Technologies", the following calculations are performed:

A. Calculate initial inoculum in spores per gram waste.

2×10^{10} spores/15 lbs. waste =
2×10^{10} spores/6.8×10^{4} grams waste =
3×10^{6} spores/gram waste = inoculum = IC.

$IC = 3 \times 10^{6}$

B. Calculate number of spores recovered.

1. Step One "Control" Data:

	a	b	c
Plate A	TMTC*	TMTC	TMTC
Plate B	TMTC	TMTC	TMTC
Plate C	TMTC	TMTC	TMTC
Plate D	200 cfu**	210 cfu	190 cfu

*Too Many To Count
**Colony Forming Units

Accounting for the dilution factor of 10,000 for Plate D, the average recovery of viable "Control" spores per gram equals 200 x 10,000 or 2,000,000 spores/gram or 2×10^{6} spores/gram.

$RC = 2 \times 10^{6}$.

2. Step Two "Test" Results:

	a	b	c
Plate A'	50 cfu	48 cfu	52 cfu
Plate B'	5 cfu	4 cfu	6 cfu
Plate C'	1 cfu	0 cfu	0 cfu

The average recovery of viable "Test" spores per gram equals 50 spores per gram (no dilution factor).

$RT = 5 \times 10^1$

C. Calculate Log_{10} Reduction.

1. Step One "Control" Results:

$Log_{10}RC = Log_{10}IC - Log_{10}NR$; where:
$Log_{10}RC = Log_{10}(2 \times 10^6$ spores/gram) = 6.301
$Log_{10}IC = Log_{10}(3 \times 10^6$ spores/gram) = 6.477
$Log_{10}NR = Log_{10}IC - Log_{10}RC$
$Log_{10}NR = 6.477 - 6.301 = 0.176$

$Log_{10}NR = 0.176$.

2. Step Two "Test" Results and Log_{10} kill Calculation:

- a) Log_{10} kill = $Log_{10}IT - Log_{10}NR - Log_{10}RT$, where:

$Log_{10}IT = Log_{10}IC = 6.477$
$Log_{10}NR = 0.176$
$Log_{10}RT = Log_{10}(5 \times 10^1) = 1.699$

- b) Log_{10} Reduction (Log_{10} kill), where:

Log_{10} kill = $6.477 - 0.176 - 1.699 = 4.602$
Log_{10} kill = 4.602

C

EXISTING MEDICAL WASTE TREATMENT TECHNOLOGIES

Note: This is only a partial list of technologies. The information presented here is constantly changing. Therefore, it is highly recommended to use other sources for searching out all available potential vendors.

Type of Technology	Company and Location
Autoclave	
	Aegis Bio-Systems, L.L.C. 3324 French Park Drive, Suite A Edmonds, OK 73034
	Bioclave Systems 161 Ward Court Lakewood, Colorado 80228
	Bondtech Corp 2404 Bardstown Rd Louisville, KY 40205
	Environmental Tectonics 125 James Way Southampton, PA 18966
	Hydroclave Systems 1371 Middle Rd., Kingston, Ontario, Canada K7L 5H6
	Lajtos TDS 28, rue Sebastopol 59100 Roubaix - France
	The Mark-Costello Co. 1145 E Dominguez St # Carson, CA 90746

Type of Technology	Company and Location
	Occigerm 250, Ancienne Route de Cavillargues 30330 Connaux - France
	R.E. Baker SIERRA INDUSTRIES, INC. 1021 South Linwood Ave. Santa Ana, CA 92705
	San-I-Pak, Inc. 23535 South Bird Road P.O. Box 1183 Tracy, CA 95378-1183
	Tempico, Inc. 251 Highway 21 Madisonville, LA 70447
	Tuttnauer USA Co., Ltd. 33 Comac Loop, Ronkonkoma, NY 11779
Chemical/Enzyme/Encapsulation	
	Bio Conversion Technologies Tucker, GA 30084
	Circle Medical Products, Inc. 3950 Culligan Avenue, Suite D Indianapolis, IN 46218
	DI/AN Controls, Inc. 530 West St Braintree, MA 02184
	Isolyser Company 650 Engineering Dr Norcross, GA 30092
	M.C.M. Environmental Technologies Ltd. Moledet,M.P. Gilboa 19130, Israel
	MedCompliance Services 5307 El Paso Drive El Paso, TX 79905
	Kvaerner U.S. Inc. Successor to Medclean Technology Inc. 116 Roddy Avenue South Attleboro, MA 02703-7974

Type of Technology	Company and Location
	Medwaste Technologies Corp. 6830 N Eldridge Pkwy # 110 Houston, TX 77041
	OBF Industries, Inc. 2719 Curtiss Street Downers Grove, IL 60515
	Premier Medical Technology 9800 Northwest Freeway, Suite 302 Houston, TX 77092
	Safetec of America 1055 East Delevan Avenue Buffalo, NY 14215
	Sterile Technology Industries, Inc. 1155 Phoenixville Pike, Unit 105 Park Valley Corporate Center Westchester, PA 19380
	Steris Corp. 5960 Heisley Road Mentor, OH 44060
	Unitrade Ltd. PO Box 644 Corona Del Mar, CA 92625
	Waste Reduction, Inc.(WR^2) 212 Pinewoods Avenue Troy, NY 12180
	WESCO (Formerly Winfield - Condor Medical Waste Treatment System) 114 Fourteenth St., Suites B&C Ramona, CA 92065
Wet or Dry Heat/Electrothermal Radiation	
	The Antaeus Group 1 Northpark Drive , Suite 108 Hunt Valley, MD 21030
	Biosterile Technology, Inc 4104 Merchant Road Fort Wayne, IN 46818

Type of Technology	Company and Location
	MDS Nordion 447 March Road Kanata, Ontario Canada K2K 1X8
	MediVators, Inc. 2995 Lone Oak Circle, Suite 10 Eagan, MN 55121-03878
	PMA Services Inc. 22347 La Palma Ave. Ste. 106 Yorba Linda, CA 92887
	Stericycle, Inc. 1419 Lake Cook Road, Suite 410 Deerfield, IL 60015
	Thermal Waste Technologies 19 Stony Hill Road Bethel, Connecticut 06801
Microwave	
	CMB, Ltd. Mechanical Engineering Environmental Technology and Marketing Plabutscherstrasse 115, A-8051 Graz, Austria
	Meteka Medizinalbedarf Entwicklungs - Erzeugungs- und Handelsges.m.b.H. A-8750 Judenburg, Burggasse 108 Judenburg, Austria
	Roatan Medical Technologies, Inc. PO Box 227377 Dallas, Texas
	Sanitec, Inc 26 Fairfield Place. West Caldwell, NJ 07006
Plasma/Pyrolysis/Gasification	
	BIO-OXIDATION SERVICES INC., a division of Harsco Corp., 613 Third Street Annapolis, MD 21403

Type of Technology	Company and Location
	PEAT, Inc. 4914 Moores Mill Rd Huntsville, AL 35811
	Plasma Pyrolysis Systems, Inc. 105 Jordan Road, NY 12180
	VANCE IDS, Inc. 7382 Chancellor Dr Orlando, FL 32809
	Vanish, Inc. 6300 Highlands Court Ponte Vedra Beach, FL 32082

D

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Document D.2 D2. Microbiological Efficacy Testing. STI Model 2000, Clinical Waste Treatment Process and Requirements for Annual Process Efficacy Testing. August 2003.

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MICROBIOLOGICAL EFFICACY TESTING

STI MODEL 2000 CLINICAL WASTE TREATMENT PROCESS

&

REQUIREMENT FOR ANNUAL PROCESS EFFICACY TESTING

Prepared for Sterile Technologies Ireland Ltd.

AUGUST 2003

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Microbiological Efficacy Testing of the STI Model 2000 clinical waste treatment process and the requirement for Annual Process Efficacy Testing

A Report prepared for
Sterile Technologies Ireland Ltd.

August 2003

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STI/PETDB/200308/MGH/ver2

EXECUTIVE SUMMARY

The STI model 2000 process has been repeatedly proven to achieve the required level of microbial inactivation both in commissioning tests, further microbiological testing to demonstrate inactivation in hypodermic needles, and ongoing weekly spore testing by two independent laboratories. Daily spore tests are also carried out by STI.

The results of these tests have proven conclusively that the STI Model 2000 process can achieve the required level of inactivation (STAATT level III, or 4 $\log_{10}$ reduction in *B subtilis* spores) and can reproducibly achieve STAATT level IV inactivation, which is 100 times greater than required.

Microbiological studies have demonstrated the operating parameters at which the process can reproducibly achieve the required level of inactivation, which is acknowledged to provide a margin of safety, and has shown which operating parameters fail to achieve the required level of inactivation.

Latest guidelines from the USA recommend that, once a technology has been successfully microbiologically commissioned, further biological indicator testing is not required.

In the UK, current guidelines recommend a 6 month period following microbiological commissioning where weekly spore tests are performed, but following successful conclusion of this, this requirements may be relaxed.

I would support the requirement for ongoing spore testing rather than relying entirely on parametric monitoring.

I do not believe that a requirement for 'process efficacy testing' to be repeated annually is supported by the published guidelines or recommendations in the field of clinical waste treatment.

INTRODUCTION

This report has been produced for Sterile Technologies Ireland ltd.

In line with international licensing requirements and licensing requirements in England[1], Wales and Scotland[2,3], new technologies for the treatment of clinical waste must undergo microbiological validation testing to prove the efficacy of the system[4].

These tests are best carried out under the auspices of an experienced microbiologist and must demonstrate efficacy to internationally agreed criteria. [4,5,6]

The STI plant in Dublin has had these initial tests performed by competent laboratories, and have been proven to be capable of achieving the required level of microbial inactivation.[8]

STI have been asked to provide microbial validation testing, referred to as 'process efficacy testing' on a yearly basis. This is microbiological testing similar to repeating the original microbial commissioning and validation testing.

STI have questioned the need for this testing and have asked me to prepare this report to inform the decision making process in this respect.

BACKGROUND

With the emergence of a number of new, alternative technologies for the treatment of clinical waste in the United States, there developed a need to regulate these technologies and to ensure that they actually made the waste safe by inactivating pathogenic micro-organisms within it. The evolution of microbial efficacy testing was thus initially driven by state agencies responsible for environmental or healthcare matters as a response to US federal government legislation.[5,9]

The development and use of these alternative technologies raised concerns regarding the potential for occupational health and safety problems, as well as environmental damage caused by their operation at healthcare facilities and commercial treatment centres. [9]

In 1994, a group of experts in America (STAATT) including representatives from environmental and public health agencies of approximately 15 states published a report outlining some of the important factors that must be considered before a new clinical waste treatment process can be licensed. [4]

This report defined four levels of microbial inactivation (I to IV) as follows:

Table 1

Level I	Inactivation of vegetative bacteria, fungi and lipophilic viruses at a 6 $\log_{10}$ reduction or greater
Level II	Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 $\log_{10}$ reduction or greater
Level III	Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 $\log_{10}$ reduction or greater; and inactivation of *B stearothermophilus* or *B subtilis* spores at 4 $\log_{10}$ reduction or greater
Level IV	Inactivation of vegetative bacteria, fungi and lipophilic/hydrophilic viruses, parasites, mycobacteria and of *B stearothermophilus* spores at 6 $\log_{10}$ reduction or greater

Adoption of level III criteria as the minimum required for clinical waste treatment processes was recommended by STAATT.[4]

STAATT also emphasised that in order to establish proper testing protocols that incorporate the recommended criteria and meet any applicable recognised testing standards, an independent laboratory should be used, which is experienced in microbiological testing techniques and is familiar with the required sampling and testing protocols (ref 4 p21 para 2).

Since 1994, many other regulatory bodies have followed the guidance of STAATT and have adopted the recommendations therein (ref 9 p 3). Thus, the microbiological efficacy testing protocols have been accepted and promoted as correct by the

Environment Agency (EA) in England and Wales[1], NHS Estates (HTM 2075)[6], the Scottish Environmental Protection Agency (SEPA) and the NHS in Scotland[2].

RECENT DEVELOPMENTS

Since the publication of the STAATT report in 1994, new technologies have been developed and new questions have been raised, therefore a second meeting of STAATT was held in 1998 and a second report was produced (STAATT II)[10] which included several modifications to the original report in the light of new knowledge and experience. This report has not been as widely published as the first one, and therefore not all of the new recommendations have, as yet, been incorporated into other guidelines.

Given the status of STAATT as the most widely accepted and authoritative source on alternative technologies for treating clinical waste, it is only a matter of time before these modified recommendations are incorporated in other guidelines.

REPRESENTATIVE BIOLOGICAL INDICATORS FOR MICROBIOLOGICAL EFFICACY TESTING

STAATT (1994) felt that spores of *B stearothermophilus* and *B subtilis* were the most chemically or thermally resistant biological indicators available (ref 4 p7 para 5). They were already used as indicators of medical product sterility because of this documented resistance (ref 4 p8 para 7).

The committee concluded therefore that the evidence available demonstrated that either *B stearothermophilus* and *B subtilis* spores could be used to represent vegetative bacterial, fungi and mycobacteria in evaluating both chemical and thermal treatment systems (ref 4 p7 para 2) and could therefore be used as representative biological indicators.

The demonstration that highly resistant spores from either of these species can be effectively destroyed by a treatment process ensures a margin of safety from the variables inherent in the treatment of clinical waste (ref 4 p9 para 1).

It was suggested that if a challenge of 1×10^4 Bacillus spores was treated, retrieved and cultured, then no growth would demonstrate a 4 $\log_{10}$ reduction (ref 4 p16 para 3), which would demonstrate achievement of STAATT level III .

Thus the Environment Agency in England and Wales also recommends STAATT level III criteria as the minimum required for clinical waste treatment,[1] and the NHS in Scotland also require the demonstration of a 4 $\log_{10}$ reduction in *B subtilis* spores.[2,3]

The Environment Agency suggested that the use of some of the pathogenic strains would not be required if spores of *B stearothermophilus* and *B subtilis* could be

obtained commercially in 'ready to use' form and proposed that inactivation of these spores is sufficient alone to demonstrate inactivation of the other organisms. (ref 1 p 64 para 2).

STAATT II agreed that level III inactivation criteria were still the most appropriate to demonstrate adequate treatment of clinical waste by new technologies.[10]

The STI plant in Dublin has been proven to meet STAATT level III inactivation criteria with B subtilis spores [7,8].

MICROBIOLOGICAL EFFICACY TESTING

In 1994, STAATT also differentiated the microbial testing protocols that should be used for validation of the efficacy of a new technology that had never been tested elsewhere (technology approval), and those required for the siting of a technology that has been operating elsewhere and has been validated elsewhere (site approval) on a new site.[4]

In this light, STAATT recommended that the rigor of the biological indicator testing required for the establishment of a treatment technology for site approval would be less than the testing required for technology approval (ref 4 p24 para 2).

MICROBIAL EFFICACY TESTING FOR TECHNOLOGY APPROVAL

In 1994, STAATT recommended that for technology approval, representatives of all the different microbial groups in table 1 should be tested and proven to be inactivated to the required level (Ref 4 p 13 para 2,4 and p22 para 10), although they noted that many of these organisms had the potential to be pathogenic.

However, STAATT II has modified this requirement to recommend that only Bacillus spores and Mycobacterium species are required for initial technology approval, as the use of additional biological indicators to demonstrate the efficacy of treatment systems provides no additional safeguards to public health and safety. [9,10]

The requirement to demonstrate 6 $\log_{10}$ inactivation of Mycobacteria and 4 $\log_{10}$ inactivation of Bacillus spores is still considered valid. [9,10]

The STI Model 2000 is in use in various parts of the world and has been extensively microbiologically validated in the United States. All these tests have proven that the system can reproducibly achieve STAATT level III inactivation or greater.[7,8,11,12]

These tests were conducted in compliance with the US Environmental Protection Agency regulations or guidance, with a range of vegetative bacteria, fungi, viruses, parasites, mycobacteria and bacterial spores and have met the required criteria (table 1) in each case.

Thus the STI plant at Dublin is not a new technology and does not require the rigor of new technology testing [1,4,10].

MICROBIAL EFFICACY TESTING FOR SITE APPROVAL

In contrast, it was recommended by STAATT in 1994, that for site approval, only the demonstration that bacterial spores could be inactivated to the required level, under typical waste load conditions, was necessary (ref 4 p24 para 2 and 4).

The Environment Agency in England and Wales also recommended this approach (ref 1 p 64 para 3)

STAATT II, in 1999 have made different recommendations however.

Stating that "once a technology has successfully met the initial efficacy test requirements, additional testing with biological indicators, either when first sited at a facility or as part of a regular quality control program, would not be required". [9,10]

"If a technology effectively demonstrated 4 and 6 $\log^{10}$ reductions of biological indicators within three different surrogate test loads under specific parameters, eg time, pressure, temperature, chemical concentration etc., then it follows that if these parameters are achieved that the system must be effectively treating waste. Consequently, only parametric monitoring would be required for validation and quality control testing". [9,10]

In addition, it was concluded that the testing of 'treated waste' for micro-organisms was not necessary or useful. [9,10]

The STI Dublin plant would therefore require only the demonstration of bacterial spore inactivation to STAATT level III for site approval under the old STAATT guidance, but under STAATT II recommendations would not need microbiological testing at all [4,10].

The STI Dublin plant has been proven to meet STAATT level III inactivation criteria with B subtilis spores. [7,8,]

PERIODIC USER VERIFICATION

In 1994, STAATT also recommended that user verification methodology is necessary to periodically verify to the equipment user and the state that the treatment unit is functioning properly, that proper operating procedures are used, and that performance standards are achieved (ref 4 p27 para 2).

This specifically required the equipment user to :

- Demonstrate on a periodic basis that the required resistant bacterial endospores (*B stearothermophilus* or *B subtilis*) are inactivated to level III criteria under standard operating procedures.

- Document the frequency of biological and parametric monitoring

- Document and record all biological indicator and critical parametric monitoring data

The Dublin STI plant carries out daily in-house *B subtilis* spore tests, the results of which are available for examination. The testing methods used conform to STAATT [4,10], Environment Agency in the UK[1] and World Health Organisation[13] requirements.

The frequency of these tests and the results are recorded, as are the parametric data.

The requirements of STAATT and the UK Environment Agency have been fulfilled during the operation of the STI Dublin plant [1,4,10].

STAATT (1994) also recommended that parametric monitoring could substitute or replace biological indicator inactivation monitoring if the following conditions were achieved (ref 4 p24 para 1):

- The process must have tamper-proof controls or automatic factory-set controllers
- Be integrated with the treatment unit to automatically shut down or no longer accept or expel waste if treatment conditions are not maintained at specified performance levels
- Be calibrated periodically as specified by the monitoring device's manufacturer
- Provide a tamper-proof recording of all the critical operating parameters

These conditions have been met by the STI plant in Dublin.

The Environment Agency in England and Wales also recommended this approach (ref 1 p 70 para 8)

However, the UK Environment Agency also recommended that, after commissioning, in addition to parametric monitoring, microbial inactivation be demonstrated not less than once weekly using bacterial spores. If this reliability of inactivation is demonstrated through 6 months of normal operations, this frequency may be reduced at the Agency's discretion (ref 1 p 71 para 6).

The STI Dublin plant has had daily microbial inactivation tests using spores of *Bacillus subtilis* performed both in-house and by an external independent laboratory. In-house tests have all proved the process capable of achieving STAATT level III or greater inactivation[7] since November 2000, and external laboratory testing has confirmed these as valid in 2002[7].

The STI Dublin plant has more than fulfilled this requirement for demonstration of microbial inactivation with daily spore tests. The results of these tests prove that the process can reproducibly inactivate clinical waste to the required level over a sustained period of time[7].

PARAMETRIC MONITORING

In 1994 STAATT recommended that proper correlation be made between parametric monitoring (such as steam pressures, temperatures, residence times, auger speeds etc) and biological indicator inactivation through documented studies linking microbial inactivation with the parameters being monitored (ref 4 p23 para 3 and 4)

The Environment Agency in England and Wales[1] and NHS Estates[6] have also recommended this approach.

In 1999, STAATT II produced further recommendations, where parametric tests alone were considered sufficient for ongoing monitoring following satisfactory microbiological commissioning, as long as the agreed parameters were maintained, and ongoing biological tests were not required.[10]

The STI plant at Dublin has had satisfactory microbiological commissioning and under STAATT II guidelines could be monitored on parametric controls alone.

DISCUSSION

The STI Model 2000 clinical waste treatment plants in Ireland have been extensively microbiologically tested and validated by independent laboratories and have been proven to reproducibly achieve STAATT level IV inactivation of *B subtilis* spores (ie 100 times the required level of inactivation) when the operating parameters were set correctly.

It is worthy of note that clinical waste contains fewer micro-organisms than domestic waste, and the same types of pathogenic micro-organisms may be present in both[1]. Some studies have shown that household waste contains on average 100 times more micro-organisms with pathogenic potential than hospital waste[14] therfore the achievement of STAATT level IV inactivation does provide a great margin of safety.

This has allowed experts in the field to conclude " we can deduce from our daily exposure to household waste and the decades of sanitary landfill burial, that the public health risks for the less microbiologically contaminated hospital waste are nominal"[14].

The American Centre for Disease Control has stated "there is no epidemiological evidence to suggest that current health waste disposal practices have caused disease in the community[15].

The STI model 2000 treats waste at greater than 80°C for around 1 hour on average at normal operational parameters. This is proven by direct measurement of temperature within the unit using a datalogger.

Evaluation of the scientific literature shows that with the exception of bacterial spores, all other micro-organisms are completely inactivated at temperatures of around 80°C[1].

Given the above, it is not logical to subject clinical waste treatment plants, which have been proven to consistently meet an extremely high level of microbial efficacy under established operating parameters, to repeated validation testing which adds nothing to the existing body of evidence.

The requirement for 'process efficacy testing' to be repeated annually is not supported by the guidelines or recommendations of any of the recognised authorities in the field of clinical waste treatment.

The independent microbiological efficacy tests that have already been carried out on the STI model 2000 process in the United States and in Ireland have conclusively proven that the system can consistently achieve the required treatment level with the stated operating parameters, and the ongoing microbiological monitoring has confirmed this over a much longer time and with much greater frequency than is recommended in any guidelines.

I have personally been involved in the microbiological efficacy testing of 19 separate clinical waste treatment processes, and no other regulatory body has required annual process efficacy testing.

It is my belief that annual process efficacy testing by an independent laboratory is not necessary in a system so well proven as the STI model 2000 and adds nothing to the body of information already in existence regarding the efficacy of the process.

If an annual revalidation is a real requirement, I would suggest that a better way would be for an independent consultant to audit the results obtained over the year by the daily in-house spore tests and any external microbiological testing performed.

In line with STAAT and UK Environment Agency guidelines, a permanent record of key operating parameters such as Auger speed, steam pressure and chamber temperature could be kept and this could be correlated with the results of spore tests.

This could also be audited annually and would provide much more valuable information on the efficacy of the system.

I would however, support the continuation of the on-going spore tests currently performed, as I have some concerns over the reliance on parametric controls alone. It is possible that the frequency of these tests might be reviewed in the light of the extremely good results achieved over the operating life of the plant so far.

CONCLUSION

The STI model 2000 process has been proven conclusively and repeatedly to achieve the required level of inactivation (STAATT level III, or 4 $\log_{10}$ reduction in *B subtilis* spores) and can reproducibly achieve STAATT level IV inactivation, which is 100 times greater than required.

As even STAATT level III is acknowledged as providing a margin of safety [1,4,5,6,9] the STI process must be regarded as capable of safely treating clinical waste under set operating conditions.

The STI model 2000 process is monitored parametrically and using spore tests on a daily basis, thus correlating the microbial efficacy of the system with parametric measurements, as recommended.

The STI process has been tested more than any other alternative clinical waste treatment system that I am aware of, and certainly more than regulatory bodies in the United States, England, Scotland and Wales require.

Given the accumulated microbiological test results available on the STI model 2000 system, I do not believe that annual process efficacy tests are warranted, and I can not see how they can add anything to the current level of knowledge.

I recommend that annual process efficacy tests be discontinued.

If an annual review of the systems performance is required by the regulatory body, I recommend that an independent consultant audit the test results obtained from in-house and independent spore testing over the year. This would provide a much more in-depth picture of overall efficacy than a simple repeat of commissioning tests.

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Document D.2 D3. Microbial Pyramidal Life.

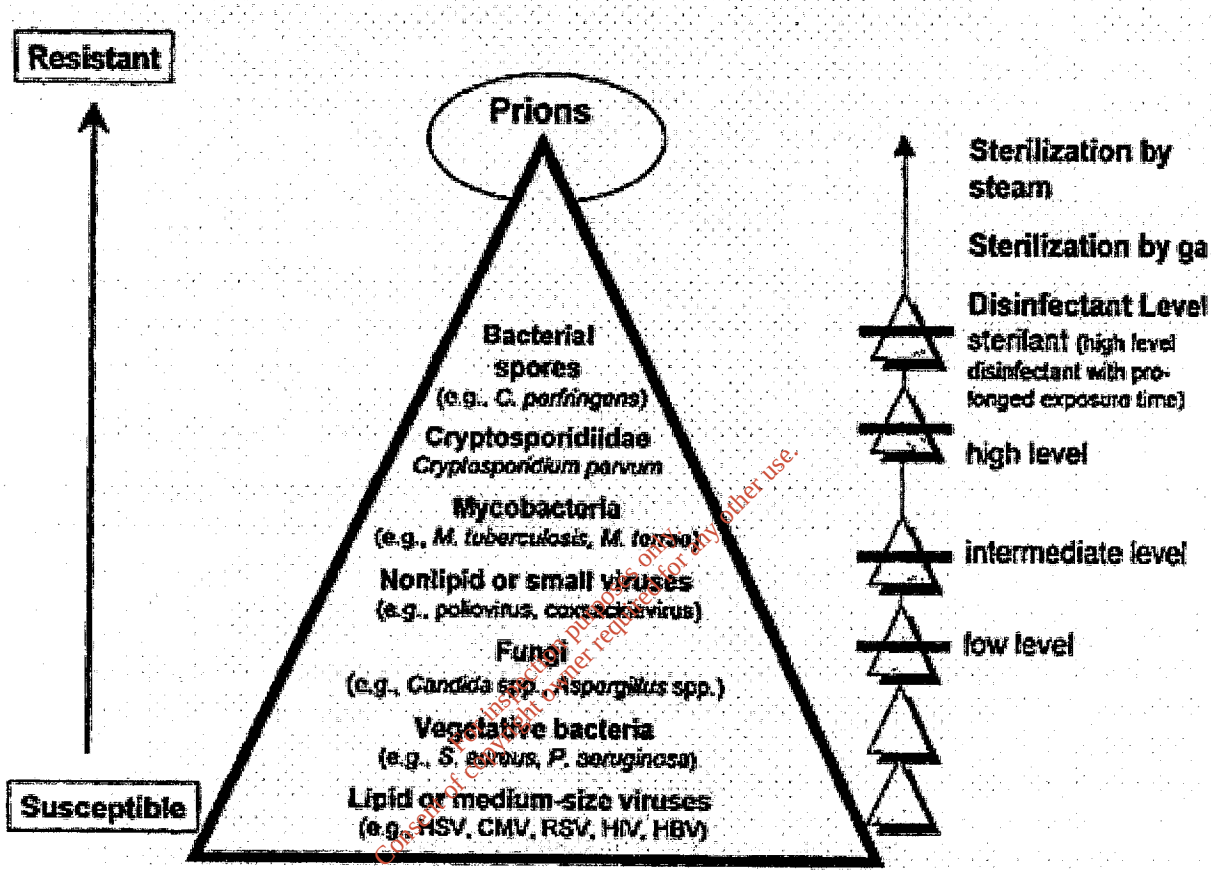


FIGURE 1 Increasing order of resistance of microorganisms to disinfectants.

Figure D.2 F1 – Waste Treatment Process Flow sheet – Collections

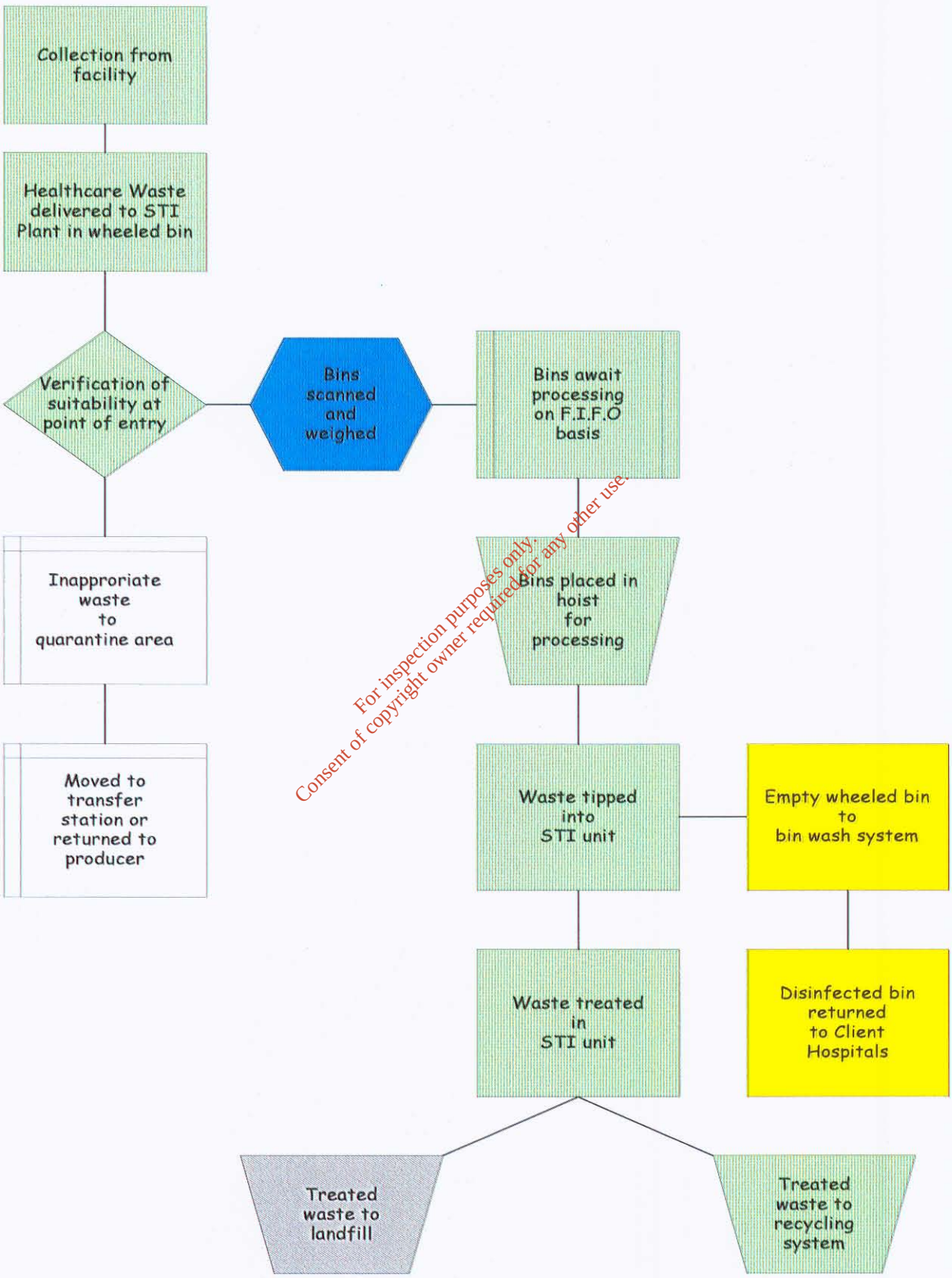


Figure D.2 F2 – STI Model 2000 Operation Flow sheet - Treatment

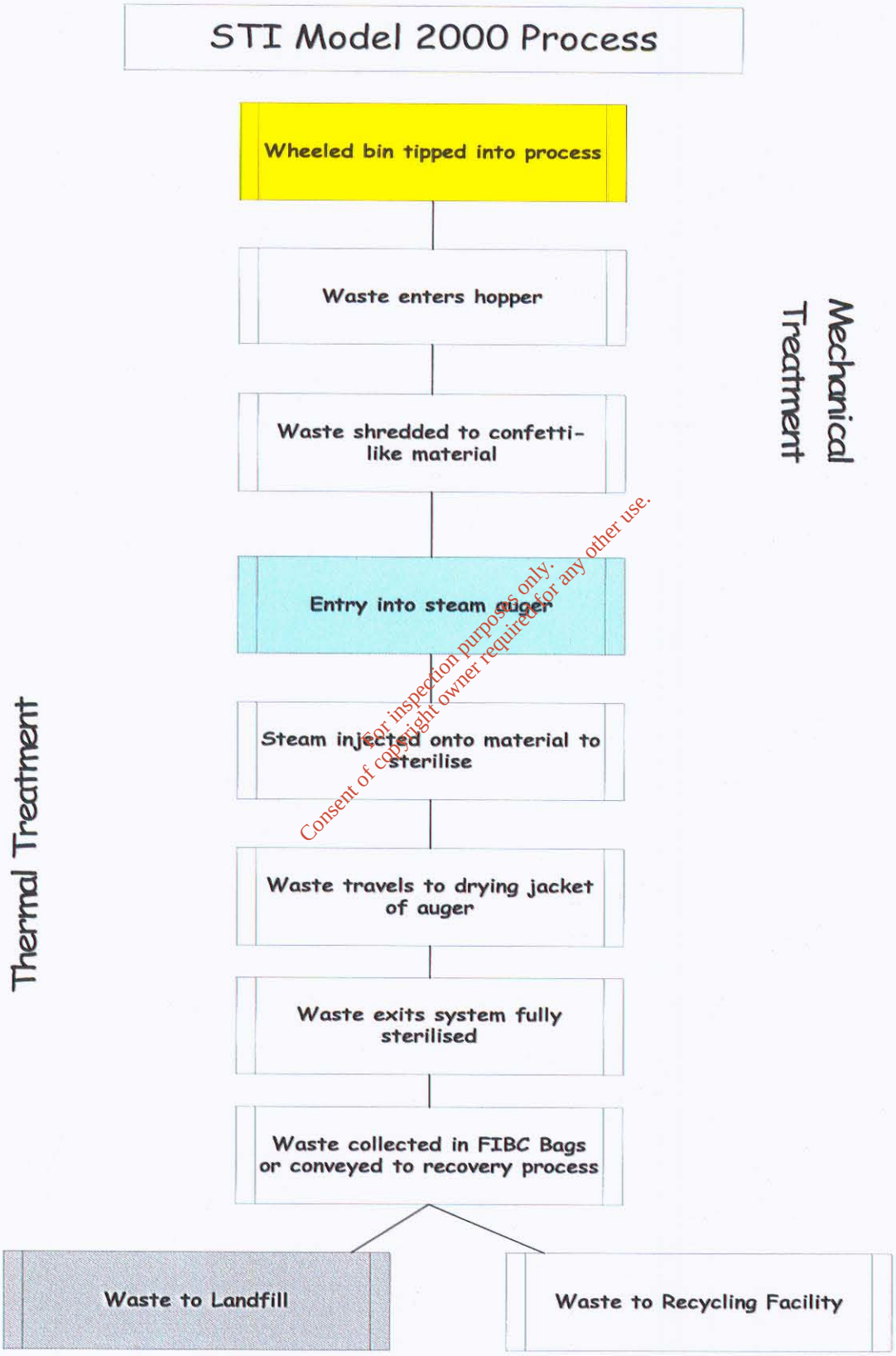
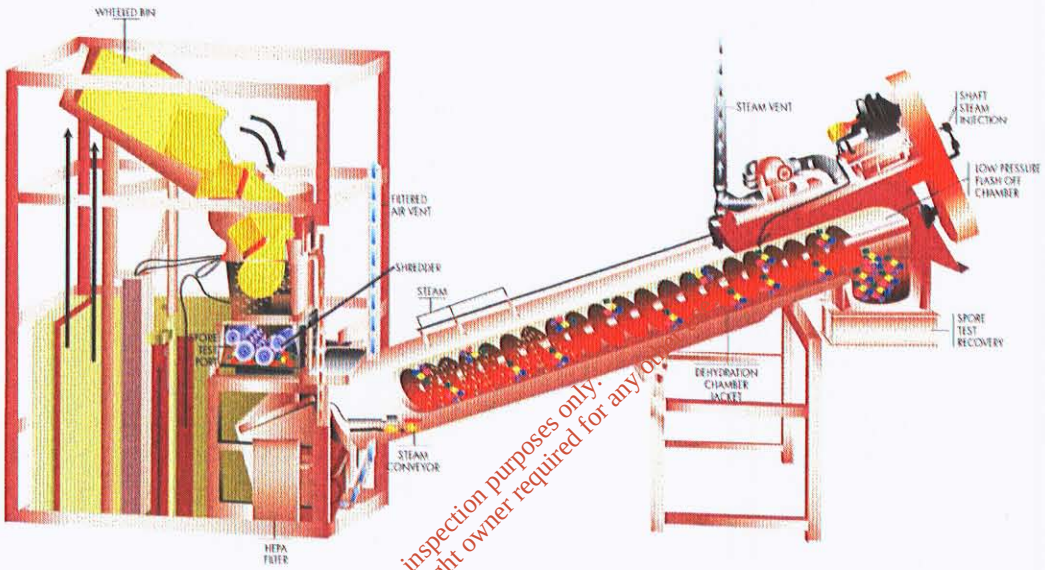


Figure D.2 F3 – STI Series 2000 Operation Schematic



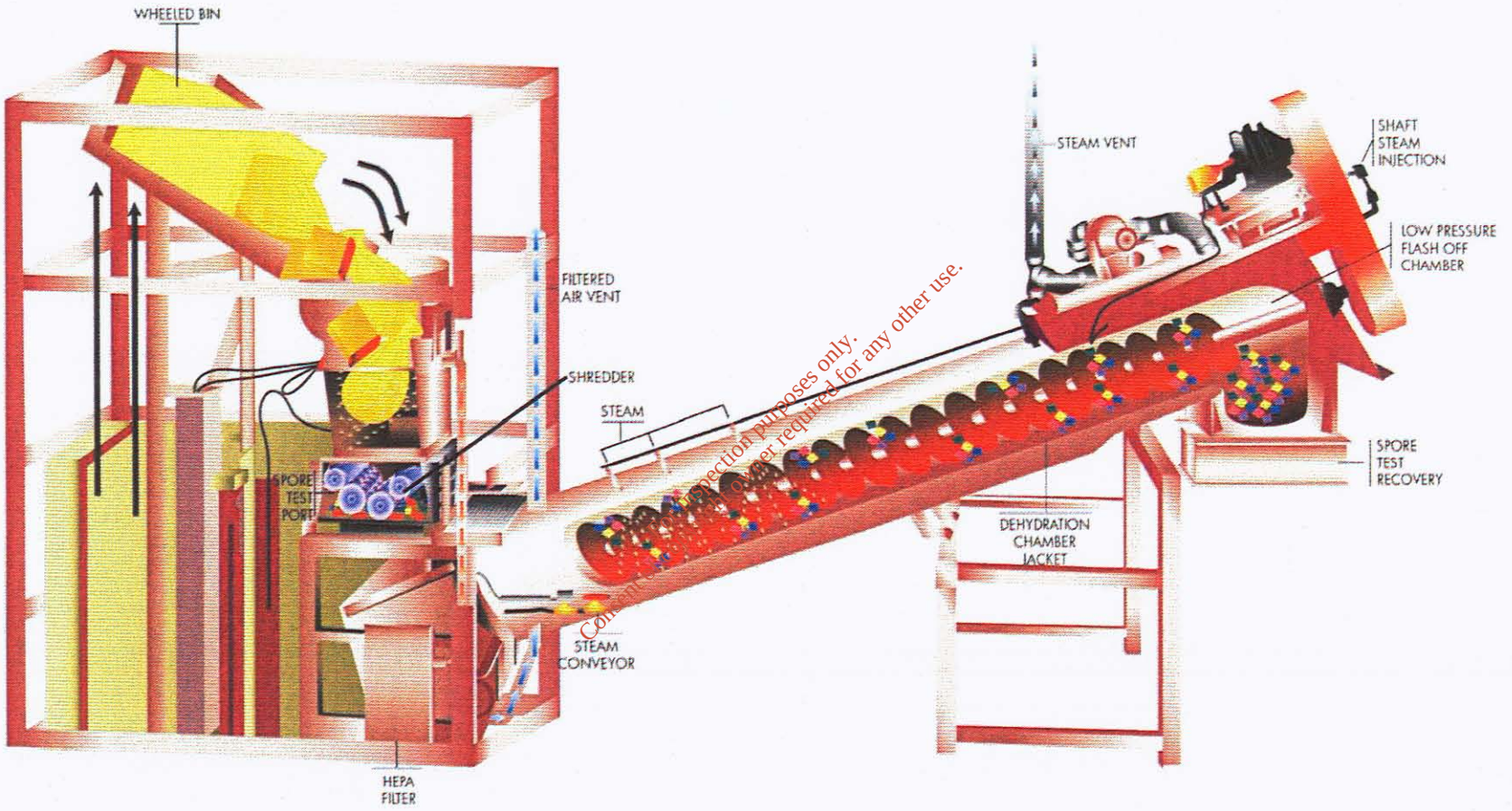


Figure D.2 F4 – Bin Wash Operation Flow sheet

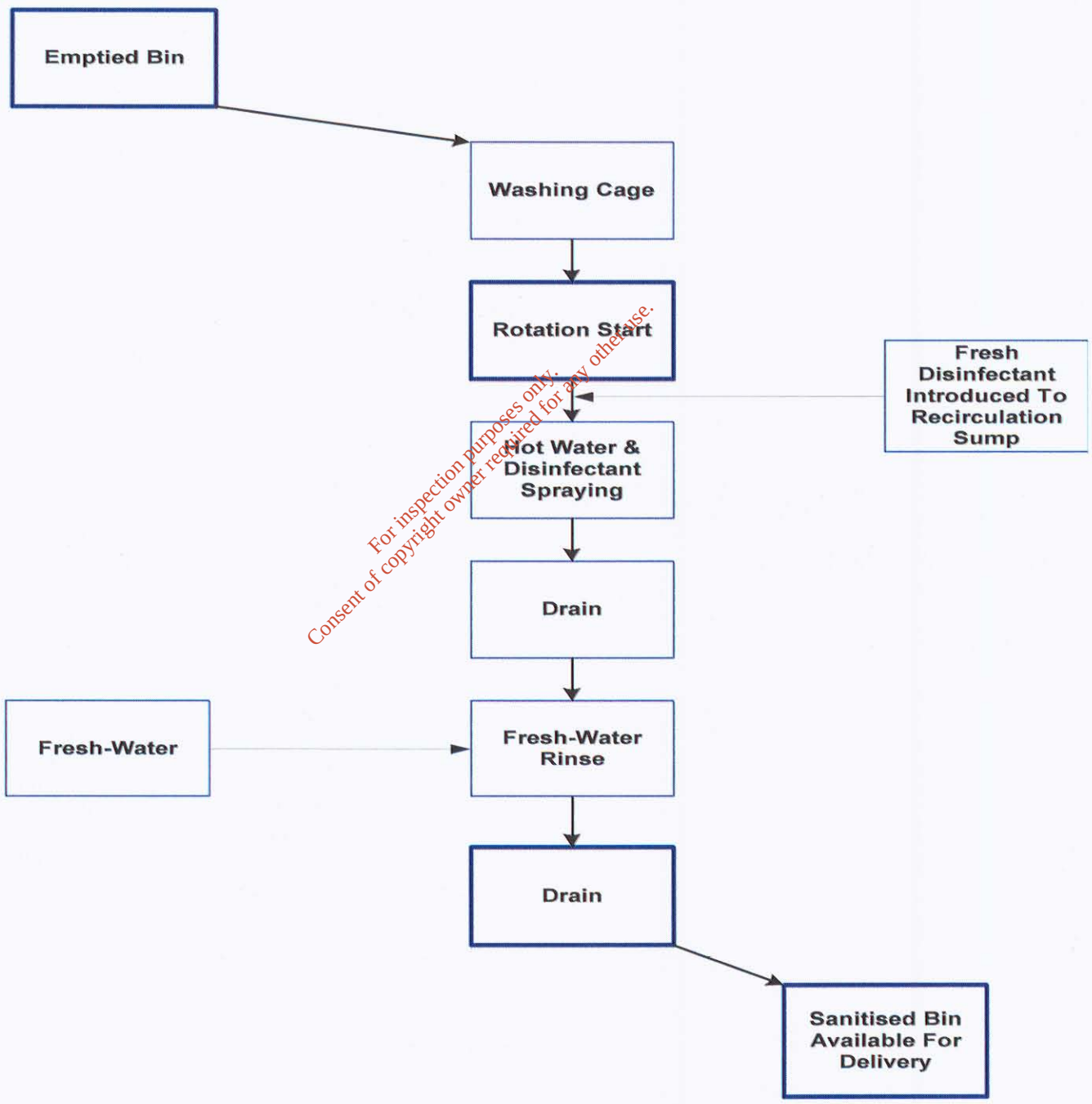


Figure D.2 F5 – Waste Transfer Process Flow sheet

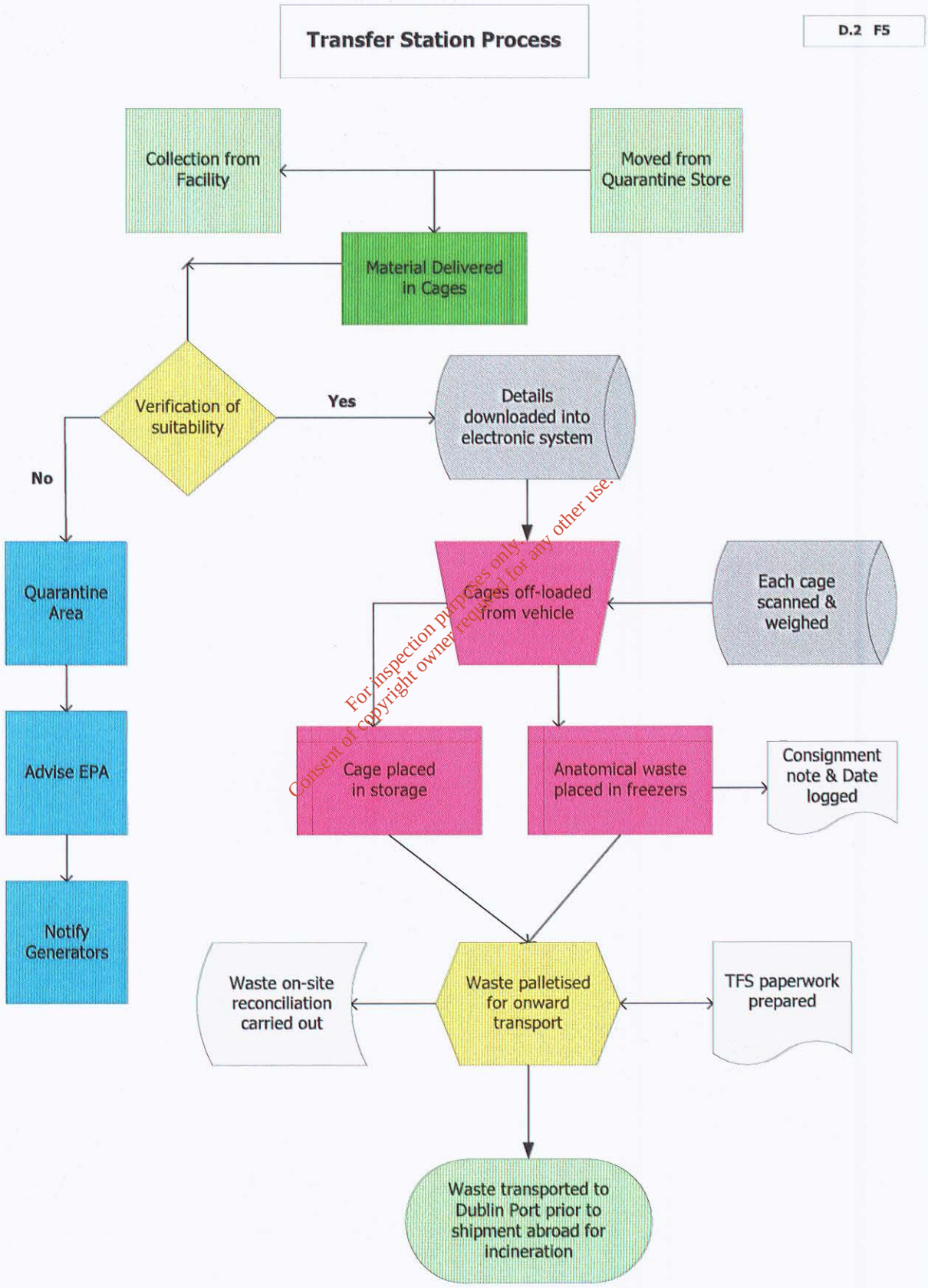


Figure D.2 F6 – Waste Recovery Process Flow sheet