The committee recommended that efficacy testing protocols and all results of any evaluations conducted, including original data, be included for evaluation by the state agency reviewing the application for treatment technology approval. The methodologies and protocols developed are especially critical for state evaluation of medical waste treatment processes that pulverize, grind, or shred the waste during the treatment process and do not allow intact retrieval of the biological test indicator. The complexity of these protocols is illustrated in Appendix C, "Example: Treatment Efficacy Testing Protocol for a Grinder/Chemical Medical Waste Inactivition Process".

To establish proper protocols that incorporate the recommended criteria above and meet any applicable recognized testing standards will, in most likelihood, require the equipment manufacturer to seek assistance from an independent laboratory. To ensure the required quality control and facilitate state review of the treatment process, the committee recommended that the qualified laboratory selected should:

- Be experienced in microbiological testing techniques and be familiar with required sampling and testing protocols;
- Be an accredited laboratory or have experience with product registration through the federal Food and Drug Administration (FDA) or the USEPA Office of Pesticide Programs; and
- Be equipped to meet FDA "Good Laboratory Practices" requirements.

3.2 Approval of Medical Waste Treatment Technologies

As a first step in the review process, information is required of the manufacturer to provide the state with the information it needs to properly assess the treatment technology proposed for approval. The state's use of a comprehensive information request form is essential in obtaining relevant information and in acquainting the manufacturer with the requirements and the responsibilities inherent in the review process. To meet these objectives, the form should at a minimum:

- Delineate state responsibilities and permitting requirements;
- Delineate manufacturer responsibilities and registration requirements;
- Request 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, temperatures, pressures, chemical concentrations, irradiation doses, feed rates, and waste load composition;

- Request documentation demonstrating that the treatment method meets microbial inactivation criteria and required testing protocols, including a detailed description of the test procedures and calculations used in fulfilling designated performance standards verifying efficacy, of user verification methodology, and of microbial culturing protocols that ensure traceability, purity and concentration;

- Provide documentation of applicable emission controls for suspected pathological and toxics emissions; and

- Provide documentation for occupational safety and health assurance by describing the medical waste treatment equipment's safety systems such as warning signage, operating zone restrictions, lock-out procedures, and personal protection equipment requirements.

To assist the committee in developing a format for an information request form, information forms from the states of California, Michigan, and New Jersey were reviewed for their content. In addition to the information requested on these forms, the committee recommended that the following information also be requested:

- A more extensive discussion on available parametric controls (to verify efficacy and ensure operator non-interference in the treatment process);

- A discussion on energy efficiency and other potential benefits the treatment technology has to offer to the environment; and

- More detailed information relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling.

From the forms reviewed and the additional information requested by the committee, a recommended informational request form, termed an "Application for Evaluation and Approval of Medical Waste Treatment Technologies", was developed (See Appendix B).

In addition to fulfilling environmental and occupational safety requirements, all treatment technologies must meet Level III efficacy criteria. Demonstration that these criteria are met is the responsibility of the equipment manufacturer. In meeting these requirements the manufacturer must:

- Demonstrate that all required pathogen surrogates and resistant bacterial endospores (as recommended in Table II) are inactivated to Level III criteria under all required challenge waste load compositions;

- Develop and demonstrate that site approval and user verification testing protocols are workable and valid; and

- Demonstrate where technically practical, the relationship biological indicator data and data procured from real-time parametric monitoring equipment.

To assist in presenting the recommendations for efficacy review, an approval process guideline is presented in Appendix A.

3.3 Parametric Monitoring and Controls

Parametric monitoring of a medical waste treatment process can provide real-time data acquisition for assessing efficacy. However, correlation of the data acquired from the parametric monitoring device(s) with that of biological indicator studies is essential if parametric monitoring is to supplement or replace biological indicator monitoring. This demonstration is the responsibility of the manufacturer (vendor). To verify that a proper correlation has been established between the parametric monitoring device and biological indicator inactivation, the manufacturer (vendor) must demonstrate that parametric monitoring is:

- Correlated with biological indicator inactivation through documented efficacy studies linking microbial inactivation with the parameter(s) being monitored;

- Accurately monitoring the treatment agent and/or treatment conditions, as applicable (i.e., provide the limiting conditions that influence accurate monitoring); and

- Appropriate for the conditions that exist under operational circumstances.

Demonstration of the above components may allow the use of parametric monitoring for auditing treatment conditions or alerting the equipment operator of equipment malfunction or abnormal behavior. However, the use of parametric monitoring to substitute or replace biological indicator inactivation must require the device to additionally:

- 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; and

- Provide a tamper-proof recording of all critical operating parameters.

The committee recommended that parametric monitoring could substitute or replace biological indicator monitoring provided that all of the above conditions were achieved.

3.4 Site Approval for Medical Waste Treatment Technologies

The purpose of the site-approval process is to ensure that the treatment equipment sited is the same equipment and process approved by the state. Site approval may also require obtaining other state permits (i.e., solid waste treatment/disposal permits; emissions and discharge permits) in addition to those required under state medical waste regulations. Technology efficacy must also be demonstrated under actual operating conditions. However, the rigor of the biological indicator testing would be less than the testing required for technology approval, although tests conducted would be required to reflect the waste load compositions of waste treated. Effectiveness and reliability of the real-time monitoring systems must also be demonstrated to receive site approval. Additionally, agency review is necessitated to verify proper and safe operations, verify disposal of waste residues, and verify operator training.

Specifically, to fulfill microbial inactivation and information requirements recommended for site approval, the equipment user must:

- Demonstrate that required resistant bacterial endospores (as recommended in Table II) are inactivated to Level III criteria under typical waste load and challenge compositions;

- Verify that user verification protocols adequately demonstrate effectiveness of the treatment process;

- Verify the relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment (i.e., correlation of biological indicator inactivation with time and temperature via thermocouple monitoring);

- Document in a written plan,

  - Names or positions of the equipment operators
  - Waste types or categories to be treated
  - Waste segregation procedures required
  - Wastes types prohibited from treatment
  - Equipment operation parameters
  - Efficacy monitoring procedures
  - Operating documentation and record-keeping requirements
  - Contingency waste disposal plans
  - Personal protective equipment requirements

- Shut-down, clean-out and maintenance procedures
- Emergency response plans
- Operator training requirements; and

- Provide for state review,

  - Equipment model number and serial number
  - Equipment specification and operations manual
  - Certification that equipment is identical to state approved system
  - User's written plan
  - Certification documentation of operator training.

The state may want to visit the site of proposed operation to validate operations, or approve the site by reviewing the submitted information and documents. As a condition of site approval, the state should affirm its right to inspect the facility and affirm 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 plan.

Recommendations for the site approval process are presented in the approval process guideline in Appendix A.

3.5 USEPA Pesticide Use Registration

The use of a chemical agent in any treatment process may involve pesticide registration with the USEPA Pesticide Registration Office under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The USEPA Pesticide Registration Office's involvement in the regulatory process is dependent on advertising claims made by the medical waste treatment equipment's manufacturer (vendor). If claims are made that specify a level of microbial inactivation by term (i.e., kills pathogens, disinfects), registration with the USEPA Pesticide Registration Office is required.

Registration for a label claim will require the manufacturer (vendor) to submit efficacy studies of the process for review. Currently, the only label claim allowed for any medical waste treatment technology is the claim of "sanitizer", which is defined as "an antimicrobial agent that is intended for application to inanimate objects or surfaces for the purpose of reducing the microbial count to safe levels."

Several questions remain to be addressed concerning the involvement of the USEPA Pesticide Registration Office in the medical waste treatment technology review process. These questions are summarized as follows:

- For what advertising claims (and by which media, e.g, newspaper, product labels, etc.) should federal pesticide registration be required for chemical treatment processes?

- What are the specific guidelines and protocols required or what information is necessary for efficacy assessment review by USEPA Pesticide Registration Office?

- What are the quality assurance/quality control requirements required for pesticide registration?

- What potential conflicts may arise from the microbial inactivation guidelines recommended by the committee and those claims allowed by the USEPA Pesticide Registration Office?

It was recommended that the committee continue its dialogue with the USEPA Pesticide Registration Office to ensure consistency in the regulatory review process.

4.0 PERMITTING AND STATE AUTHORIZATION ISSUES

Although the review process for medical waste treatment technology approval is primarily concerned with ensuring safe and effective medical waste treatment, several permitting issues were identified and discussed by the committee. Recommendations are summarized below for each issued discussed.

4.1 User Verification: Biological Inactivation Efficacy Monitoring

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. 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 microbial inactivation and documentation requirements recommended for user verification, the state operating protocol will require that the equipment user to:

- Demonstrate on a periodic basis that required resistant bacterial endospores (as recommended in Table II) are inactivated to Level III criteria under standard operating procedures;
- Document the frequency of biological and/or parametric monitoring; and
- Document and record all biological indicator and critical parametric monitoring data.

Although no formal verification of compliance with these recommendations was prescribed, the committee noted that numerous regulatory agencies (i.e., the federal Occupational Safety and Health Administration, the state department of health, the state environmental agency) and accrediting associations (i.e., Joint Commission on Accreditation of Healthcare Organizations, College of American Pathologists) would serve to provide oversight. User verification requirements recommended are contained in the "State Guideline for Approval of Medical Waste Treatment Technologies" presented in Appendix A.

4.2 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, efficacy monitoring, and permitting might be necessitated to ensure that microbial inactivation is maintained and that environmental and occupational/public health and safety concerns are met.

As a facility applying for a commercial medical waste treatment permit, additional requirements may be imposed under other solid or special waste treatment/disposal regulations. As such, cooperative efforts between permitting agencies or divisions are 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 committee recommended that the potential use of the technology be indicated in technology review information supplied to the state by the equipment manufacturer.

4.3 Previously Approved Technologies

With rapid evolution of emerging medical waste treatment technologies and with the establishment of more restrictive efficacy criteria, previously granted approvals become an issue. Within the framework of the approval or permitting process, some mechanism should be established that requires previously approved technologies to meet current efficacy criteria. A number of options should be available to the state to allow previously approved mechanisms to continue with the realization that at some point, previously approved technologies will have to meet current standards. The committee discussed several options that would allow the state to periodically review all medical waste treatment technologies to determine if they were fulfilling current standards of performance.

Option One involved the granting of approval for a technology with the provision that any modification to the equipment would require reapplication for approval under current standards. As an example, the State of New York Department of Health in its approval letter includes 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."

Option Two 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 on the issuance of the new medical waste 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 were discussed as to whether they should be included as an "emerging treatment technology." It was noted that the 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 presently do not consider steam sterilization to be a new technology and do not require any additional approval as such. It was recommended by the committee that steam sterilization not be included as an "emerging treatment technology" and thus, not be subject to registration and technology approval requirements. Site and operation permits would still be necessitated, as required, under applicable state regulations.

The committee, 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:

  - sterilization cycle time, temperature, and 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; and

- Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results.

4.4 Small Medical Waste Treatment Devices

As stated previously, the committee took the position that Level III criteria were applicable to all medical waste treatment devices, including small "counter-top" devices. It was recognized by the committee that registration of all small medical waste treatment devices by the authorized state regulatory agency would be a significant effort in states which do not already have generator and disposal facility registration requirements. To minimize the state's effort, it was 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 for 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 for the user to ensure proper equipment use, operational safety, and treatment technology efficacy. These materials and documents would include:

- An operations and maintenance manual;
- Information on proper use, safety precautions and the implications of potential misuse;
- Efficacy testing instructions;
- A training/education manual; and
- Available service agreements/programs.

On 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 would be submitted annually to the state by the manufacturer as the notification record of site registrations of equipment installed that previous year. The committee recommended that small medical waste treatment devices be specifically identified on initial application for technology approval.

4.5 Waste Residue Disposal

The disposition of waste residues was an environmental concern expressed by many on the committee. To ensure that waste residues are properly identified and disposed of, the committee recommended 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:

- 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); and
- Recycling efforts, if anticipated (i.e., waste types, amounts, percentages, name and location of recycling effort).