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 also 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; and
- 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 steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed of as general solid waste after verification of microbial inactivation.

4.6 Operator Training

Mandated operator training was recommended (as appropriate: small treatment devices may be excluded from this recommendation) as a requirement for process approval because of its potential affect on both efficacy and operator safety. To assure proper operation of the treatment process, the manufacturer would be required to provide an operator training program which would include:

- Training and education materials adequately describing the process, process monitors, and safety precautions and controls;
- Contingency plans in the event of abnormal occurrences (e.g., power failure, jamming, inadequate chemical concentrations) and emergencies (e.g., fire, explosion, release of chemical or biohazardous materials);
- Shut-down, clean-out and maintenance procedures;

- Personal protective equipment requirements; and

- 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 committee 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 medical waste treatment technologies.

4.7 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: acceptable waste types, loading parameters, process monitors, treatment conditions, and disposal;

- A description of all parametric controls and monitoring devices, their appropriate settings, established ranges and operating parameters as correlated with biological indicators, and calibration requirements;

- A description of the methods required, both to ensure process monitoring instrumentation is operating properly and to prevent tampering with controls;

- 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 (e.g., power failure, jamming, inadequate treatment conditions) and emergency conditions (e.g., fire, explosion, release of chemical or biohazardous materials);

- A description of personal protective equipment requirements for routine, abnormal, and emergency operations;

- A thorough description of all potential occupational safety and health risks posed by the equipment and its use;

- Specific responsibility assignments for operators:

  - Collecting and organizing data for inclusion into the operating record;
  - Evaluating any discrepancies or problems;
  - Recommending actions to correct identified problems; and
  - Evaluating actions taken and documenting improvement.

4.8 Emergency and Contingency Response Plan

The development of a separate plan to assist the operating facility in properly responding to an unplanned, emergency, or abnormal event was recommended by the committee. The development of the plan will by necessity, be a shared responsibility between the manufacturer (vendor) and the equipment's user. 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 biological and/or chemical agent exposure to the equipment operator or other support or maintenance personnel; and

- 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 (e.g., inadequate chemical agent concentration, temperature);

- Mechanical failure (e.g., jammed shredder, inadequate steam pressure);

- Equipment shut-down in mid-cycle;

- Spill or release of biological or chemical agents; and

- Accumulation of untreated or inadequately treated medical waste.

As the equipment designer, the manufacturer (vendor) should provide evidence of a failure mode and effect analysis to prevent or minimize inadequate treatment and biological/chemical exposures caused by equipment, process design, process control, and process monitoring failures. This analysis should examine all possible and expected effects of failures, specifying in detail the nature of the effect and causes of action to be taken to prevent biological/chemical exposures. The analysis must examine the effects of failure related to:

- All process controls and process monitoring devices, their appropriate settings, and established ranges and operating parameters;

- All parametric controls and associated monitoring devices, their appropriate settings, and established ranges and operating parameters as correlated with biological indicators, and calibration requirements;

- Proper mechanical and equipment responses, including identification of system upsets or malfunction (e.g., power failure, jamming, inadequate treatment conditions) and emergency conditions (e.g., fire, explosion, release of chemical or biohazardous materials);

- The methods required, both to ensure process and parametric monitoring devices are operating properly and to detect tampering with the devices;

- The methods and schedules for periodic calibration of process and parametric control and monitoring instrumentation; and

- Equipment/inadequately treated waste decontamination procedures required in the event of a mid-cycle shut-down.

The equipment user has the responsibility of incorporating the manufacturer-supplied information into a descriptive written emergency and contingency response plan. Additional information to be provided in the plan should at a minimum 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; and

- A pre-designated disposal method and site for untreated or inadequately treated medical waste if an equipment failure precludes use of the treatment equipment.

5.0 RESEARCH AND DEVELOPMENT

The issue of state responsibility and regulation in the research and developmental phase of medical waste technologies was raised. It was recognized 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 process of establishing research and development variances, including limitations and allowances;
- The knowledge of and permitting of potential environmental emissions and safety considerations;
- Treatment process residue disposal; and
- Agency funding and staffing.

Because of the above concerns, it was the consensus of the committee that each state view as optional its participation in experimental medical waste treatment research and development projects. For those states opting to participate in medical waste treatment technology research and development projects, the concerns raised above were discussed.

To provide a framework for discussion, the committee reviewed language currently proposed by the State of Illinois Environmental Protection Agency (IEPA) for "Experimental Permits" for medical waste treatment technologies. Language as proposed states that the "Agency may issue Experimental Permits" provided that the "applicant can provide proof that the process or technique has a reasonable chance for success." Additionally the IEPA requires evidence that "environmental hazards are minimal" and requires a "description of the type of residuals anticipated and how they will be managed and disposed of." As proposed, the Experimental Permits are to be granted for two years with a one-time renewal based on submittal of application of renewal and a report summarizing equipment performance, efficacy results, and management of residual materials.

In the discussion that followed, the question was raised of how proof can be provided that the equipment has a "reasonable chance of success." It was suggested that proof may consist of data acquired from scaled-down prototypical models or from analogous technologies that have a proven track record. It was noted from the prior discussion that IEPA stated it 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 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 as steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed of as general solid wastes on verification of microbial inactivation. Non-treated medical wastes used during research and development would require agency-approved treatment after testing.

Concern that the research and development permit might be used as a mechanism to operate a commercial waste treatment venture was also raised. It was suggested that to avoid this possibility the following statements 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 on state approval of the process;
- Research and Development permitted facilities cannot accept waste for monetary gain; and
- 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 was also a concern. It was emphasized that the additional requirements of time, staff, and expertise to monitor and review the experimental technology would require that some mechanism (e.g., set fee or time and materials) be established to reimburse the state for these activities.

6.0 RECOMMENDATIONS FOR FUTURE ACTIVITIES

It was the committee's hope that these discussions and resultant report would be useful in establishing a nationally recognized foundation for the review and approval of emerging medical waste treatment technologies. To provide future support for the development and implementation of a nationally recognized guideline, the committee recommended:

- The establishment of a research program to evaluate the thermal, chemical and irradiation resistance of B. subtilis and B. stearothermophilus spores relative to all representative microbial groups for the determination of their use as ultimate pathogen surrogates for medical waste treatment technology efficacy testing;

- 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 establishment of criteria and testing procedures to monitor the potential release of biological aerosols from alternative medical waste treatment equipment;

- Establishment of a clearinghouse to create a network for:

  - 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; and

- 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.

7.0 SELECTED BIBLIOGRAPHY

Agency for Toxic Substances and Disease Registry. "The Public Health Implications of Medical Waste: A Report to Congress". U.S. DHHS, Public Health Service, Atlanta, Georgia, 1990.

"AOAC Guide to Method Format and Definition of Terms and Explanatory Notes". In: Helrich, K., ed. Official Methods of Analysis of the Association of Official Analytical Chemists, 15th ed., AOAC, Inc. 1990.

American Public Health Association et al. Standard Methods for the Examination of Water and Wastewater. 18th Ed., 1992.

American Society of Mechanical Engineers (ASME). "Proposed ASME QMO-1 Standard for the Qualification and Certification of Medical Waste Incinerator Operators". April, 1992.

Beloain, A. "Disinfectants". In: Helrich, K., ed. Official Methods of Analysis of the Association of Official Analytical Chemists, 15th ed., AOAC, Inc. 1990.

Centers for Disease Control. "Biosafety in Microbiological and Biomedical Laboratories", 3rd ed., 1993.

Bond, W.W., Favero, M.S., Peterson, N.J., and J.W. Ebert. "Inactivation of Hepatitis B Virus by Intermediate-to-High Level Disinfectant Chemicals". J. Clin. Microbiol. 18:535-538. 1983.

Favero, M.S. "Sterilization, Disinfection, and Antisepsis in the Hospital". Manual of Clinical Microbiology. 4th Ed. American Society of Microbiology. 1985.

Favero, M.S. and W.W. Bond. "Chemical Disinfection of Medical and Surgical Materials". In: Block, S.S., ed., Disinfection, Sterilization and Preservation, 4th Ed. 1991.

Illinois EPA. Notice of Proposed Amendments, Title 35, Subtitle M, Chapter I, Subchapter b: Potentially Infectious Wastes, Part 1420-1440. March, 1993.

Spaulding, E.H. "Chemical Disinfection and Antisepsis in the Hospital". J. Hos. Res. 9:5-31. 1972.

USEPA, Office of Pesticide Programs. "Pesticide Assessment Guidelines. Subdivision G - Product Performance." September, 1982.

USEPA. Test Methods for Evaluating Solid Waste, Physical/Chemical Methods. EPA Publication SW-846. Third Edition, 1986 as amended by Update I, November, 1990.

40 CFR Part 259 "Standards for the Tracking and Management of Medical Waste". Federal Register 54 (56): 12326. March 24, 1989.