STAATT III

Executive Summary
and Daily Discussions
Orlando, Florida
December, 2005

STAATT

STAATT III CONFERENCE
DECEMBER 5-7, 2005

PREFACE

A meeting was held in Orlando in December, 2005, to discuss the new developments which had occurred since the 1998 publication of the STAATT II Guidance Report on the processing of medical waste. Participants included local, state and federal regulators, as well as representatives of companies that manufacture and/or operate treatment technologies.

The Executive Summary of the STAATT III Meeting describes the most important issues on which consensus were achieved by those in attendance. In addition, more detailed summaries of the conference discussions are included to provide a more complete understanding of the wide range of topics and issues considered by the participants, including the recommendation to require the same efficacy data for autoclaves as for any other type of treatment technology. The areas of consensus and recommendations which emerged from this meeting will form the basis for the complete revision of previous STAATT reports. The forthcoming STAATT III Guidance Report, which will be available by the end of 2007 in electronic and hard copy formats, will provide all involved in the medical waste industry with updated information on the most complex and continuing issues concerning this special waste stream. In addition, the report will offer clear guidance to both regulators and vendors on areas ranging from applications for approval of treatment technologies to "Z" values of bacterial spore biological indicators.

If after reading the summaries you have questions, comments or recommendations, please direct them to Ira F. Salkin (irasalkin@aol.com), Edward Krisiunas (ekrisiunas@aol.com) or Joe Delloiacovo (delloiac@optonline.net).

STAATT III CONFERENCE
DECEMBER 5-7, 2005
EXECUTIVE SUMMARY

Meetings were held in Orlando, FL from December 5 – 7, 2005 to review and revise the information contained in the STAATT I (April, 1994) and STAATT II (December, 1998) guidance documents. The following are the more significant recommendations reached at the meetings:

Introduction

Conference participants were recognized experts in the evaluation and testing of medical waste treatment technologies from state and federal agencies, as well as representatives of governmental organizations within the United Kingdom and technology vendors (see attached list of participants). Several key issues were reviewed and discussed including new information on potential treatment limitations of steam autoclaves, detailed presentation on the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), guidelines for evaluating air emission generated by various types of treatment technologies, and additional recommendations on approving treatment systems based on more realistic conditions likely to be encountered in their actual operation at healthcare, research and commercial facilities.

Though several of the participants hold official positions in state and federal agencies, this document does not necessarily represent the policies or recommendations of any of the state/federal agencies or commercial concerns that the participants represent.

STAATT guidelines have become widely recognized as an industry source of scientific knowledge and experience and used as an important tool by regulators throughout the US and around the world. This document should be used as a guide to the methods and procedures that may be employed in the evaluation and approval of treatment technologies.

Treatment Technologies

Autoclaves

During the STAATT I and II conferences autoclaves were not considered "emerging" or "alternative" technologies. However, the current consensus is that autoclaves be included under the broad umbrella of medical waste treatment technologies. As such, they must meet the same standards in efficacy/validation testing as any other treatment systems, especially if used for the treatment of suction canisters, human pathological waste, animal carcasses, and/or other thermally resistant waste materials, e.g. items within sharps containers or material wrapped in tyvek plastic. Operational parameters should continue to be determined through discussions between vendors (or on rare occasions, the operator) and regulators, but the parameters should never be below those established in efficacy testing by vendors/operators of treatment systems.

However, in the majority of states, the operating standards are based on the century old practices employed in the sterilization of medical devices, i.e., those that are employed within the sterile environment of the human body. It was the general consensus that effective treatment of medical waste creates a different set of challenges

for autoclaves than do medical devices. Presentations by several participants of their own investigations indicated that the efficacy of autoclaves was dependent upon many variables including, but not limited to, the composition, density, liquid content, weight, and types of containers of the loads as they all affect the physics of heat transfer and steam penetration. In certain instances, the efficacy of autoclaves was found to be less than the minimum standards recommended by STAATT. In addition, types of biological indicators, e.g., genus and species of bacterial spores, their "D" values, the placement of the indicators in the load, as well as the methods used to determine the temperatures both within the autoclave and the test loads could affect the selection of the operating parameters by the vendors and operators. These observations raise questions as to the "standard" operating parameters used by autoclaves in the treatment of medical waste and suggest that vendors and users conduct efficacy studies that incorporate the multiple variables that present significant challenges to the autoclave's capability to effect treatment.

In-Situ Chemicals – Suction Canisters

The attendees recommended that the federal Environmental Protection Agency adopt the same efficacy requirements as employed in the evaluation of any type of treatment technology for those chemicals used in the *in situ* treatment of the contents of suction canisters. If the vendors of products that chemically encapsulate components of the medical waste stream, i.e., sharps, body fluids, etc., make claims that such encapsulation treats these items, then it was the general consensus that the treatment capabilities of these products be held to the same standards as any other system.

Furthermore, it was noted that suction canisters and similar items in the medical waste stream present a unique challenge to the capabilities of any technology that does not preshred the containers. A presentation made during the conference on independent testing indicated that those systems that ruptured rigid containers, e.g., suction canisters, were effective in the treatment of contents of the containers. However, if rigid containers were not broken by the technologies and their liquid contents were not integrated into the waste loads, inconsistent or unsuccessful treatment of the liquids was found. Based upon these and other findings discussed, the attendees recommended further exploration of the issues created by suction canisters in their treatment by thermal and chemical based systems.

Chemical Treatment System

A representative of the EPA's antimicrobials group presented the following key points regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):

- If a technology is an instrument or contrivance that inactivates microorganisms on medical waste, then the technology is considered a device and FIFRA registration is not required;
- If the technology employs a chemical or substance that inactivates microorganisms on medical waste, then the chemical in the technology is considered a pesticide and FIFRA registration is required;
- A pesticide device is not required to be registered under FIFRA;
- However, that same device is regulated under FIFRA; and

- It is against the law for anyone to sell or distribute chemical pesticides without EPA labeling. To obtain FIFRA registration, chemical vendors must present data from efficacy tests that demonstrate a 4 Log_{10} inactivation of bacterial spores and a 6 Log_{10} inactivation of mycobacteria vegetative cells.

High Heat Technologies

Discussions also focused on the evaluation of plasma arc and pyrolysis technologies. Both are high heat systems that do not involve direct exposure of the waste to a flame (which sets them apart from incineration according to US EPA regulations). Plasma arc reduces waste to molten slag, while pyrolysis breaks down waste at high heat in the absence of oxygen. No sample can be recovered from plasma arc treatment, and coupled with the high temperatures that climb into the thousands of degrees, it was concluded that plasma arc units could be excepted from efficacy testing. However, since pyrolysis involves relatively lower temperature and, since there are reports of potential sample recovery from this technology, it was concluded that no similar exception be made for pyrolysis.

All Treatment Technologies

The STAATT guidance document currently recommends that the efficacy of treatment technologies be determined by subtracting the average colony forming units (CFUs) found after treatment from the average CFUs recovered from untreated control samples. These calculations were generally based upon three untreated and nine or more treated samples employed in the testing. However, it was suggested that this method may contribute to misleading results and may not allow the assessment of outliers found during studies. It was therefore suggested the application of 95% confidence interval in the calculations might provide a more accurate method for assessing the results from efficacy/validation/challenge tests. In theory, such a statistical analysis would eliminate the problems created by outliers and provide more accurate assessment of treatment technologies. However, since the numbers of samples required to calculate 95% confidence intervals and the methods to be used in these calculations could not be provided during the discussions, it was decided to postpone any attempt of reaching a consensus on the inclusion of this approach for a future meeting.

Building on the discussions during the STAATT II conference, the attendees recommended the application of parametric monitoring as a method for meeting the quality control regulatory requirements. However, it was stipulated that the parametric monitoring criteria be validated through efficacy testing. In addition, the criteria or set-points should be revalidated at regular intervals employing in most instances, biological indicators. Finally, the monitoring devices should provide permanent records from real time collection of the operating conditions.

There was consensus that regulators consider as part of their review and evaluation of treatment technologies the following environmental matters:

Aerobiology studies of areas adjacent to the treatment equipment/system	Biological and chemical testing of the liquid discharges from the equipment
Balance of air handling through the	QC of environmental factors and

technology and/or within the area where the equipment is located	equipment use to minimize potential negative environmental impacts from using the treatment equipment
Negative pressure within the system	Fixed portal radiation monitors
Application of HEPA and charcoal filters	

Microbial Inactivation and Test Indicators

There was consensus for maintaining bacterial spores and mycobacterial cells as the biological indicators in efficacy studies of all medical waste treatment technologies. In addition, it was agreed that all treatment systems must demonstrate a 4 $\log_{10}$ inactivation of bacterial spores and a 6 $\log_{10}$ reduction of mycobacteria viable cells. It was acknowledged that a small number of regulatory jurisdiction require by either statute or regulation a 6 $\log_{10}$ inactivation of bacterial spores. In addition, there are regulatory agencies that require in efficacy and/or validation tests the inclusion of additional types of biological indicators, e.g., fungi, protozoan parasites. However, evidence accumulated since the publication of STAATT II guidance report indicates that neither the inclusion of additional test organisms nor a 6 $\log_{10}$ inactivation of spores are needed to demonstrate the capabilities of any system to effectively treat medical waste. This consensus view is supported by many current reference texts, as for example, the Manual of Clinical Microbiology, 8th ed., published by the American Society for Microbiology in 2003.

There was some discussion of the lesser resistance of mycobacteria cells as compared to bacterial spores and whether or not the former indicator should be included in efficacy/validation tests. However, it was noted that mycobacteria are associated with infections of concern to users and policy makers and as such represent a real world demonstration of a technology's ability to destroy pathogens. While they are less resistant than spores, they are still more resistant than other vegetative microorganisms and remain a challenge to the efficacy of treatment systems. Furthermore, there are no reports known to attendees of treatment technologies that could effectively inactivate these two indicators but not other vegetative microorganisms. Therefore, it was recommended to include inactivation of mycobacteria as part of the proposed STAATT III report.

Since the last STAATT meeting, experience has demonstrated that spores produced by the same bacterial species with the same ATCC accession code but obtained from two different vendors may not be similar in their resistance/susceptibility to heat treatment. This and other differences in the nature of bacterial spores are now known to be due, in part, to differences in their D-values. The latter is defined as the exposure time required, under specified sets of conditions, to cause a one $\log_{10}$ or 90% reduction in the initial concentration of the biological indicator. It is an indication of relative resistance of the spores to heat or thermal treatment. Organisms of the same species and/or ATCC strain can have their D-values altered to either enhance or diminish their resistance to treatment. Some manufacturers of biological indicators provide the D-values of the spores in their products and in many instances this information is included with each spore shipment. It was the consensus that D-values should be considered as a factor in the selection of bacterial spores required in efficacy/validation testing of heat treatment technologies and that this topic be considered in future meetings.

However, since there are no comparable D-values for use with chemical treatment systems, it was proposed to use random samples from up to three separate lots of spores from each of three vendors in efficacy studies. Multiple strips/suspensions could be used as part of a single run. While this could provide an interim measure without a significant increase in cost, the attendees considered that they did not have enough information to reach a definitive conclusion on chemical D-values, or an alternative to thermal D-values.

One question brought out in the discussions was whether there were bacterial spore formers other than *Bacillus atrophaeus* (*B. subitis* var. *niger)* and *Geobacillus (Bacillus) stearothermophilus* that could be employed in efficacy/validation tests. It was noted that while the use of a bacterial strain suggested by the Association of Official Analytical Chemists (AOAC) was included in the STAATT I guidance document, those present at the conference decided not to take any final action as to recommending its use in the proposed STAATT III guidance document.

Since none of the attendees knew of any reports that indicated significant differences in the resistance/susceptibility of *Bacillus atrophaeus* and *Geobacillus stearothermophilus* spores to heat or chemical treatment, either could be employed in evaluations of treatment technologies. However, the former is more commonly employed in studies involving dry heat technologies while the latter in tests of systems that use moist heat, e.g., autoclaves.

Approving Medical Waste Treatment Technologies

There was no consensus as to a “benchmark” local, county, state or federal regulatory program whereby meeting the requirements of that jurisdiction translates to across-the-board acceptance in other jurisdictions. This presents challenges in terms of time and capital expenditures to vendors as they attempt to satisfy the requirements of each regulatory jurisdiction. In addition, the development of standard efficacy/validation test protocols remains a continuing objective due to variations in the components of the medical waste stream from state to state or even facility to facility, as well as inherent differences in medial waste treatment technologies and their respective treatment claims.

It was recommended that vendors of all treatment technologies submit their protocols to obtain approval of regulatory agencies prior to the initiation of the testing. Efficacy (to demonstrate vendor claims) and validation studies (once the system is sited) should be conducted for all medical waste treatment systems. Challenge testing or quality control can be conducted through the use of either parametric monitoring or

biological indicators provided that parametric monitors have been validated with indicators through efficacy testing and are revalidated at regular intervals as determined through discussions between regulators and vendors.

In the rare instances in which the technologies were designed and employed for purposes other than the treatment of medical waste and the manufacturers make no claims as to the capabilities of their systems to treat this waste, it becomes the operators’ responsibility to support efficacy and validation testing.

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Waste loads that typify actual waste to be processed, in terms of its components, volume, and density would provide the optimum test of treatment technologies. However, specifying a waste load or a handful of technology-specific waste loads could create false impressions as to the capabilities of treatment technologies and their use at specific facilities. In addition, the composition of waste loads vary from facility to facility, state to state and even country to country relative to the presence of fibers (natural and synthetic), plastics, paper, organic load, etc., as reported from within and outside of the United States. Therefore, it is hoped that in subsequent meetings that a description of a standard test load can be provided, but for the present, determining such a load remains a collaborative effort between the vendor (or in rare instances, the operator) and regulator.

It was the consensus of those attending that untreated controls be used whenever possible as the benchmark in efficacy and validation studies. The levels of biological indicators obtained through these controls are reflective of any losses caused by sampling methods, shipment of test materials and laboratory procedures. Therefore, these controls provide more accurate indications of initial concentrations of bacterial spores and mycobacterial vegetative cells in efficacy/validation studies than those assessed in the laboratories of the biological indicator vendors.

The attendees recommended that laboratories conducting any form of efficacy or validation tests of medical waste treatment technologies be independent of the vendors/operators of these systems. In addition, the laboratory is responsible for the chain of custody, the preparation of samples, their shipment to the test site, their collection upon completion of testing and their shipment to the laboratory for the analysis of the samples. The review of the test protocols and data generated from the tests are the responsibility of the regulatory agencies.

Future directions

Those attending the conference suggested in order to further the exchange of information and provide assistance to regulators and vendors, that a professional scientific educational organization be established. To this end, the International Society on Analytical Analysis of Treatment Technologies (IStAATT) was founded at the conclusion of the conference with the following Mission statement:

IStAATT will promote and enhance broader understanding of the collection, transport and treatment of the medical waste stream through the exchange of information by its members and with the members of other relevant professional organizations. The Society's interest will include, but not be limited to; appropriate methods for packaging

solid and liquid medical waste, on and off-site transport, appropriate biological indicators for evaluating the efficacy of treatment technologies, efficacy test protocols and procedures, methods to periodically monitor the continuing operation of treatment systems, consistent treatment standards, and related matters. The Society will sponsor education conferences on medical waste and workshop programs related the collection, transport and treatment of this waste stream. The Society will review published medical waste regulations, recommendations and guidelines, attempt to influence the contents of such documents, support appropriate standards and criteria for all phases of processing

this waste stream and act as an international focal point for the consolidation of views on these issues. The STAATT documents and format will be the foundation upon which future guidance will be issued by the Society. Through these efforts, IStAATT seeks to promote the safety of those exposed to medical waste as a result of their occupation and ensure the protection of public health and the environment from the hazards inherent in the medical waste stream.

IStAATT has as of November, 2006 been incorporated in New York State, has received its Employee Identification Number for the federal Internal Revenue Service in December, 2006 (needed to establish a separate bank account) and will soon be filling to obtain "not-for-profit – tax exempt" status. Those interested in becoming members of this fledgling organization may contact Ira F. Salkin (irasalkin@aol.com), Edward Krisiunas (ekrisiunas@aol.com) or Joe Delloiacovo (delloiac@optonline.net).

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TYPES OF TESTS

It is recommended that vendors of technologies who make claims as to the capabilities of the systems to treat medical waste obtain prior approval of their efficacy test protocols from the regulatory agency from which a permit or license is being sought. Initial efficacy testing must be conducted with biological indicators for all alternative treatment technologies and autoclaves (known hereafter as medical waste treatment technologies). Validation testing to evaluate the capabilities of the system's operator and the operation of the technology once the system is sited, should be conducted for all medical waste treatment technologies. Challenge testing or QC can be conducted through the use of either parametric monitoring or biological indicators provided that parametric monitors have been validated with indicators through efficacy testing and are revalidated at regular intervals as determined through discussions between regulators and vendors. In the rare instances in which the technologies were employed for purposes other than the treatment of medical waste and the vendors make no claims as to the capabilities of their systems to treat this waste, it would be the operators' responsibility to support efficacy and validation testing.

SUPPLEMENT FROM DISCUSSIONS ON DAY 3 – DECEMBER 7, 2005

Initial efficacy, on-site validation, and quality control monitoring should remain integral to the STAATT guidance document.

Is it acceptable to manually document data associated with parametric monitoring? This can be acceptable, but how these data are recorded and maintained are at the discretion of the regulator. While the majority of technologies available today allows for the easy collection and recording of parametric control references, it was suggested that in the event a recording device is inoperative, manually logging the data should be allowed until such time as the device is repaired or replaced. This too would be at the discretion of the regulators. It was recommended that data, if collected manually, be correlated with digitally-obtained parametric monitoring whenever practical.

Each of the STAATT documents has and will continue to be published as guidance documents. STAATT represents the consensus of a group of state regulators and other experts on the subject of medical waste treatment. The documents generated serve as a source of uniformity for draft regulations, but there is no mandate that each state use all or any part of the guidelines set forth.

Each state is responsible for setting its own regulations, and each is responsible for determining which medical waste treatment technologies may operate within its jurisdiction. There is no consensus as to a "benchmark" jurisdiction whereby meeting the requirements of that jurisdiction translates to across-the-board acceptance in other jurisdictions. This presents challenges to the vendors to satisfy the requirements of jurisdictions one by one in the form of time and capital. In addition, the development of standard efficacy/validation test protocols remains a challenge due to variations in the components of the medical waste stream from state to state or even facility to facility, as well as inherent differences in medial waste treatment technologies and their respective treatment claims.

From these discussions, it was recommended that:

1. Further effort be made to work with various jurisdictions to standardize requirements from one to the next;
2. Where practical for meeting part or all of a jurisdiction's regulations, efficacy testing for another regulatory agency should be able to be used and accepted by the former agency. As expressed:

> "*Microbiological efficacy testing, if conducted in accord with, and meeting the requirements of STAATT Guidelines, need only be conducted once. If waste composition and densities are comparable, and the proposed operating parameters are identical, the results may be submitted for license application in other states or countries.*"

3. However, it should be noted that autoclaves tested at or new sea level will operate at higher pressures to attain the same temperatures when used at higher latitudes. Therefore, one parameter (temperature) would be consistent under both conditions, but another (pressure) would have to be different at the two altitudes.

WORST CASE TESTING SCENARIOS FOR HEAT AND CHEMICAL TREATMENTS

There was consensus for maintaining a 4 Log_{10} inactivation of bacterial spores and a 6 Log_{10} reduction of viable mycobacterial cells as the criteria for assessing the efficacy of all medical waste treatment technologies. However, no consensus was achieved as to the criteria to be used in the treatment of prion-contaminated and bioterrorism-generated waste.

One question brought out in the discussions was whether there were other biological indicators that could be used in efficacy/validation/challenge testing. *Bacillus atrophaeus* (*B. subitis* var. *niger)* is more resistant to dry heat, while *Geobacillus (Bacillus) stearothermophilus* is more resistant to moist heat. However, it was noted that even a dry heat treatment system, in the presence of a wet waste, becomes moist heat technology.

Another question considered was whether a 95% confidence interval should be employed in a statistical evaluation of efficacy/validation testing data, i.e., the ability of the technologies to meet the 4 Log_{10} and 6 Log_{10} inactivation criteria. The use of such confidence intervals would diminish the possible subjectivity of microbiological methods and assist in interpreting the random failures that may be encountered with all treatment technologies. In other words, as expressed during the discussions, what do occasional outliers mean in perspective to the broad assessment of the systems? If a 3.8 Log_{10} reduction in bacterial spores is encountered, can the technologies still meet the efficacy/validation test requirements? Alternatively, do two results indicating only a 2.5 Log_{10} inactivation infer that the systems cannot meet approval standards? The consensus of those attending the meeting was that the 95% confidence interval must be interpreted on the basis of the number and severity of the failures to achieve the consensus standards.

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The worst case scenario parameters covered here, i.e., 4 Log_{10} inactivation of bacterial spores and 6 Log_{10} reduction of mycobacteria viable cells should apply to all technologies. There was a brief discussion on the lesser resistance of mycobacteria and whether or not this biological indicator should be excluded from the test parameters. However, it was iterated that mycobateria are associated with certain infections of concern, such as tuberculosis, that carry weight with users and policy makers as a real world demonstration of a technology's ability to destroy pathogens. While they are less resistant than spores, they are still more resistant than other vegetative microorganisms and remain a challenge to the efficacy of treatment systems. As such, inactivation of mycobacteria will remain a component of the proposed STAATT III report.

BIOLOGICAL INDICATORS

The following items discussed earlier were reiterated and expanded upon as follows:

- The number and type of indicators from STAATT II should be carried forth in the future STAATT III guidance report. There were additional comments regarding materials generated through bioterrorism incidents and the use of a 4 Log_{10} reduction of bacterial spores as a treatment criterion, but no consensus was achieved;
- There were no treatment systems known to those attending the meeting that could effectively inactivate bacterial spores and mycobacteria but not other vegetative microorganisms, such as fungi and viruses;
- There were no reports known to those attending of significant variation in the resistance/susceptibility between *Bacillus atrophaeus* and *Geobacillus stearothermophilus* spores to either heat or chemical treatment;
- Chemicals used in the *in situ* treatment of the contents of suction canisters should meet the same standards as other medical waste technologies (i.e., 6 Log_{10} reduction of mycobacteria and 4 Log_{10} inactivation of bacterial spores).
- Use AOAC recommended strain of bacteria species for chemical technologies noted in the STAATT I guidance report was considered, but no final action was taken as to recommending its use in the proposed STAATT III guidance document.

Exceptions to the 6 Log_{10} /4 Log_{10} test criteria were discussed for plasma arc and pyrolysis technologies. Both are high heat technologies without direct exposure of the waste to a flame (which sets it apart from incineration according to US EPA regulations). Plasma arc reduces waste to molten slag, while pyrolysis breaks down waste at high heat in the absence of oxygen. No sample can be recovered from plasma arc treatment, and coupled with the high temperatures that climb into the thousands of degrees, it was concluded that plasma arc units could be excepted from efficacy testing. Because of the lower temperature and reports of potential sample recovery from pyrolysis technologies, it was concluded that no similar exception be made for pyrolysis.

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Remarks and recommendations:

- While cast iron pipe with spore strips sealed inside can yield a charred but recoverable sample for analysis of high heat systems, stainless steel strips seeded with bacterial spores can be used as they too provide recoverable samples;
- Where references to the use of spore strips or suspensions are common in previous guidance document, it was recommended to use the term spores rather than strips or suspensions in future reports;
- While some states, such as New Jersey, recommend a 6 Log_{10} reduction of bacterial spores be achieved in efficacy/validation testing, it was agreed that the recommendations of the STAATT I committee of a 4 Log_{10} inactivation of bacterial spores be maintained in the STAATT III report. As part of the original discussions that concluded with the first STAATT guidance document, the group looked at several levels of inactivation (I through IV – see STAATT I) with increasing requirements in the level of treatment. Some wanted Level II, others III, and others IV. Level III was attainable by all alternative technologies at the time, while Level IV was unattainable. With consideration given to the disposition of the treatment waste, Level III offered sufficient kill and a safety factor to ensure protection of the public and health care workers. Level III has stood the test of time, and there have been no reported incidents of infectious disease transmission from equipment meeting Level III inactivation of microorganisms. A heightened level of treatment (i.e., Level IV) is not something that the private sector, such as landfills, is currently recommending.
- Spore strips currently available for purchase are generally not standardized for use in the evaluation of medical waste treatment equipment. Furthermore, in some states, the use of spore strips is not allowed. However, since the spore strips have been successfully used over the last 10 years, states are encouraged to allow their use when such use is practical (e.g., when spore strips can be recovered or the technologies allow for their use).

TEST LOAD COMPOSITION

Waste loads that typify actual waste to be processed, in terms of its components, volume, and density would provide the optimum test of treatment technologies. This leads to the question as to how regulators can establish a standard load considering the variability of waste generated at different facilities and differences in the capabilities of treatment technologies. Opinions differed on the typical test loads and even as to whether those that regulate medical waste should be involved in determining the composition of standard loads.

While participants from the United Kingdom have assessed waste created at healthcare facilities and identified items that would be difficult to treat, similar information is not available in the United States. Discussions continued on waste load composition

including specifying its organic content and particle size. Suggestions were made that testing be conducted with actual waste as generated at the site at which the equipment will be used. In subsequent meetings, it is hoped that a description of a standard test load can be provided, but for the present, determining such a load remains a collaborative effort between the vendor (or in rare instances, the operator) and regulator. A revision to STAATT II, section 3.2, paragraph 3, will include suction canisters to the list of examples, signifying them as a unique challenge.

SUPPLEMENT FROM DISCUSSIONS ON DAY 3 – DECEMBER 7, 2005

The composition of waste loads vary from facility to facility, state to state and even country to country relative to the presence of fibers (natural and synthetic), plastics, paper, organic load, etc., as reported from within and outside of the United States. Specifying a waste load or a handful of technology-specific waste loads could create false impressions as to the capabilities of treatment technologies and their ability to be used at specific facilities. For example, a technology which is to be used with mostly hollow plastic items may fare poorly when the actual waste stream is laden with absorbent fabric and encapsulated liquid volumes. Furthermore, claims are made as to the capabilities of a technology that may be beyond the typical parameters of that equipment's standard protocols, e.g., treatment of pathologic waste. In such circumstances, it would be necessary to incorporate all waste components claimed by a vendor (or in rare instances as described, the operator) as within the capabilities of the technology in their efficacy test protocols..

Aside from identifying a few difficult to treat items in the guidance document to be generated from this meeting, the consensus of those attending was not to recommend a standard waste load, with the expectation that medical waste generated at a facility could be used to assess treatment technologies as part of on-site validation of the equipment.

APPROPRIATE BACTERIAL CONTROLS

Since the last STAATT meeting, experience has demonstrated that spores produced by the same bacterial species with the same ATCC accession code but obtained from two different vendors may not be similar in their resistance/susceptibility to heat treatment. This and other differences in the nature of bacterial spores are now known to be due, in large part, to differences in their D-values.

The D-value is defined as the exposure time required, under specified sets of conditions, to cause a one $\log_{10}$ or 90% reduction in the initial concentration of the biological indicator. It is an indication of relative resistance of the spores to heat or thermal treatment. Organisms of the same species and/or ATCC strain can have their D-values altered to either enhance or diminish their resistance to treatment. Some manufacturers of spore strips can provide the D-values for their products and in many instances, this information is included with each spore shipment.

A range of D-values is established by the United States Pharmacopoeia (USP) for systems using steam, dry heat and Ethylene Oxide to treat medical instruments. Commercial spore manufacturers must comply with USP and FDA regulations on the

labeling of spores products and their D-values. It is the consensus that D-values should be considered as a factor in the selection of bacterial spores required in efficacy/validation testing and this topic be considered in future meetings.

However, since there are no comparable D-values for use with chemical treatment systems, it was proposed to use random samples from up to three separate lots of spores from each of three vendors in efficacy studies. Multiple strips/suspensions could be used as part of a single run. While this could provide an interim measure without a significant increase in cost, it was determined that the group did not have enough information to reach a definitive conclusion on chemical D-values, or an alternative to thermal D-values.

SUPPLEMENT FROM DISCUSSIONS ON DAY 3 – DECEMBER 7, 2005

While the inclusion of the D-value of spores may assist to standardize efficacy testing, the concept is still new for the evaluation of medical waste treatment technologies and could create confusion for both regulators and vendors. The group did not choose to include D-values in STAATT III guidance document to emerge from the meeting, but would be willing to consider a definite proposal on how D-values would be used and how D-values would factor into efficacy/validation testing at some future date to ensure that all technologies are held to the same test standards.

AUTOCLAVES

Autoclaves during the STAATT I and II conferences were not considered “emerging” or “alternative” technologies. However, the current consensus is that autoclaves be included under the broad umbrella of medical waste treatment technologies, unless otherwise specifically excluded from the STAATT III guidance report. As such, autoclaves must meet the same standards in efficacy/validation testing as any other treatment systems, especially if used for the treatment of suction canisters, human pathological waste, animal carcasses, and/or other thermally resistant materials. Operational parameters should continue to be determined through discussions between vendors (or on rare occasions, the operator) and regulators, but they should never be operated at parameters below those established in efficacy testing by vendors who claim the use of their technologies in the treatment of medical waste.

SUPPLEMENT FROM DISCUSSIONS ON DAY 3 – DECEMBER 7, 2005

In STAATT’s I and II, autoclaves were exempt from efficacy testing based on their long-standing reputation as a means of disinfection and sterilization of medical devices. However, based upon evidence presented at the meeting, the consensus of attendee’s was that autoclaves be required to meet the same efficacy/validation criteria as all other medical waste treatment systems. It was noted that the long standing history of autoclaves was not in question but rather that they be subjected to the same sort of evaluations as any other technology.

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95% CONFIDENCE INTERVAL

The STAATT guidance document currently recommends that the efficacy of treatment technologies be determined by subtracting the average colony forming units (CFUs) found after treatment from the average CFUs recovered from untreated control samples. These calculations were generally based upon three untreated and nine or more treated samples employed in the testing. However, it was suggested that this method may contribute to misleading results and may not allow the assessment of outliers found during studies. For example, what is the significance of one of the nine test samples being outside the average range and is it more significant if this outlier is one or three logs greater than the average CFUs recovered from samples? The use of a 95% confidence interval in the calculations might provide a more accurate method for assessing the results from efficacy/validation/challenge tests. In theory, such a statistical analysis would eliminate the problems created by outliers and provide more accurate assessment of treatment technologies. However, since the numbers of samples required to calculate 95% confidence intervals and the methods to be used in these calculations could not be provided during the discussions, it was decided to postpone any attempt of reaching a consensus on the inclusion of this approach until this information is obtained and circulated among participants (Please note that methods for calculating a 95% confidence interval have been received and are included at the end of this summary).

SUPPLEMENT FROM DISCUSSIONS ON DAY 3 – DECEMBER 7, 2005

Additional remarks concerning a 95% confidence interval (CI):

- If CI is accepted and recommended, it should apply to testing of all technologies;
- If CI is used, it should be employed in efficacy, validation and challenge (QC) studies. For example, over a period of a year, one QC failure may be of little concern, but additional incidents in the same or shorter periods of time may indicate a systemic problem with the technology and CI may assist in determining the cause of the failures;
- While some suggested that CI calculations could require as many as 20 or more samples, it was noted during discussions that CIs could be obtained with fewer samples, if one factors in the necessary number of standard deviations;
- There were a number of attendees either in favor of or intrigued by this proposal, but several considered that requiring the use of 95% CI calculation would be excessive given the nature of the waste stream to be treated.

SUCTION CANISTERS AND AUTOCLAVE EFFICACY

Based on surveys in California, 1.6% of suction canisters are solidified, with or without sterilants in the solidifying agent and are sent to landfills. However, an overwhelming 82.7% are treated either on-site or at commercial facilities through the use of autoclaves. A variety of suction canisters, solidifiers, and autoclaves were evaluated in order to determine if this type of technology was effective as a means of treating this unique component of the waste stream. The objective of the tests was to assess if autoclaves

could heat the contents to 250^{o}F and maintain this temperature for 30 minutes to achieve a 4 Log_{10} reduction of *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores. Spore strips in glassine envelopes were stapled to tongue depressors and the latter were positioned in the center of suction canisters prior to the addition of the solidifying agent. In addition, thermocouples were positioned to take readings at the center of the mass before the canisters were sealed. It was found in qualitative studies that test strips removed from 8 of 20 suction canisters treated at off-site facilities were positive after routine autoclave cycles. In addition, thermocouple data from 96% of the suction canisters indicated that they did not achieve, in the center of the solidified contents, sufficiently high temperatures to inactivate bacterial spores. Finally, 15 of 16 spore strips recovered from suction canisters after treatment in 5 autoclaves at 3 different medical centers were positive, i.e., spore growth was found when strips were cultured in appropriate media.

As part of a parallel study, similar test samples attached to tongue depressors were placed into suction canisters and the latter distributed at the bottom, middle, and top of test loads contained in the carts of two different large commercial autoclaves. When subjected to routine autoclave operating parameters, 0.7 to 3.9 Log_{10} reduction of *Geobacillus stearothermophilus* and/or *Bacillus atrophaeus* spores was achieved. Canisters at the bottom of the carts proved to be the most difficult to treat effectively.

Based upon the presentation of these results, attendees recommended further exploration of modifying the configuration of the waste load, as well as examining the thermodynamics of the test cycle as opposed to altering the effects of steam penetration. In addition, there is a need to conduct reproducible investigations of the treatment of suction canisters with and without solidifying agents.

A presentation was made concerning studies conducted in the UK involving the assessment of different types of treatment technologies. It was found that systems that operated most efficiently involved the rupturing of containers holding large liquid volumes, such as chest drains and suction canisters. Rigid containers that did not rupture and integrate their liquid volume into the waste load resulted in inconsistent or unsuccessful treatment of the liquids. Officials there are working to assist industry in the UK to meet existing standards.

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Several attendees on this day voiced the opinion that autoclaves were being singled out while other types of treatment technologies had not been included in these investigations. It was noted that at the time of the STAATT I and II guidance documents, autoclaves were considered to be accepted technologies and little attention was paid to their inclusion in recommendations contained in these two reports. Furthermore, the use of autoclaves in the treatment of medical waste was increasing as the application of incinerators was decreasing throughout the US. Finally, the composition of the waste stream has been changing, the use of suction canisters increasing and few investigations have ever been conducted as to the efficacy of autoclaves in treating these and other elements of the changing medical waste stream. Therefore, these studies represent the initial attempts to explore the application of autoclaves to treat medical waste, rather than the singling out of these systems.

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Several of the attendees requested additional studies be conducted, e.g., what types of autoclaves were tested (static, gravity-fed, rotational tumbling action, what pressures, what temperatures, etc.), prior to reaching any consensus on the use of autoclaves or providing any recommendations in future STAATT guidance documents. However, others felt that there were sufficient data available, preliminary or not, upon which to reach a consensus rather than waiting for additional studies which might take years to complete.

Some of those attending these discussions inquired if the concern were really regulatory in nature as opposed to evaluating the risks involved in employing autoclaves in the treatment of medical waste. For example, while suction canisters may represent the highest concentration of organic matter in the waste stream, none of those attending the conference were aware of any incident in which even one of the estimated 60 million canisters generated and treated per year around the world was linked to infection. However, very few epidemiologic studies have been conducted involving medical waste as a reservoir of infectious agents.

FIFRA

A representative of the EPA's antimicrobials group presented the following key points regarding the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):

- If a technology is an instrument or contrivance that inactivates microorganisms on medical waste, then the technology is considered a device and FIFRA registration is not required;
- If the technology employs a chemical or substance that inactivates microorganisms on medical waste, then the chemical in the technology is considered a pesticide and FIFRA registration is required;
- A pesticidal device is not required to be registered under FIFRA;
- However, that same device is regulated under FIFRA
- For clarification on any of these items, please contact Ms.Campbell-McFarlane as indicated below.

It is against the law for anyone to sell or distribute chemical pesticides without EPA labeling. To obtain FIFRA registration, chemical vendors must present data from efficacy tests involving the two types of biological indicators and these data must demonstrate a 4 Log_{10} inactivation of bacterial spores and a 6 Log_{10} inactivation of mycobacteria.

The US EPA's Antimicrobials Division is considering expanding its technical requirements to the sterilants used in suction canisters for the treatment of their organic contents. The attendees recommended that the EPA adopt the same efficacy requirements for these chemicals as for the chemicals used in treating medical waste in any technology, i.e., a 4 Log_{10} inactivation of bacterial spores and a 6 Log_{10} inactivation of mycobacteria, with a load consisting of 100% organic material within the canisters. The group is also considering specifying a 95% confidence interval. It was agreed that attendees, individually or in association with others in STAATT would assist the EPA, if requested, on this matter.

The attendees also discussed encapsulation devices, i.e., products that encapsulate components of the medical waste stream, i.e., sharps, body fluids, etc. It was the general consensus that treatment capabilities of such products be held to the same standards as any other technology, i.e., a 4 Log_{10} inactivation of bacterial spores and a 6 Log_{10} inactivation of mycobacteria. In addition, if the treatment is achieved through the use of a chemical, e.g., a sterilent or disinfectant, that FIFRA registration of the chemical must be obtained by the manufacturer.

For more information on FIFRA, including registration, the group is requested to contact Jacqueline Campbell-McFarlane of the United States Environmental Protection Agency (EPA), Antimicrobials Division, at (703) 308-6416 or Campbell-McFarlane.Jacqueline@epa.gov.

UNTREATED CONTROLS

As noted earlier in the discussions, it was the consensus of the group that the results for studies involving untreated controls be used to obtain a baseline in efficacy tests of all treatment technologies and further, that this recommendation be incorporated any guidance document to emerge from the meeting.

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Those that participated in the conference on this additional day also endorsed the use of data from untreated control studies in evaluating the efficacy of all treatment technologies.

One of the participants suggested that shredders used in some technologies to preshred the waste prior to thermal or chemical treatment could in themselves create logarithmic reductions in the concentration of biological indicators. If in fact this was the case, then such pre-treatment shredding systems would have to employ higher initial concentrations of the biological indicators to account for losses due to the shredding process.

Shredding is not recognized as medical waste treatment method and there are no studies available which would support the use of shredders as a form of treatment. The population reduction which may be observed would more likely be the result of dispersion of the waste during shredding or other non-treatment factors. The use of shredding before, during or after treatment of medical waste remains an area of concern to those attending these discussions.

The group discussed the use of the term pre-shredding and suggested that it not be used collectively to represent all options. Rather it was recommended that “internal or external destructive technologies” employed prior to the treatment of the waste replace the term. This is an area that merits further discussion and research rather internal or external destructive technologies should be used. This is an area that merits further discussion and research

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PARAMETRIC MONITORING

The consensus of the attendees was again that challenge and regular quality control testing could be conducted through either parametric monitoring or through the use of biological indicators provided that parametric monitors have been validated through efficacy testing. In addition, these criteria should be revalidated at regular intervals as determined through discussions between regulators and vendors or in the rare instances that the vendors make no claims as to the capabilities of their systems to treat medical waste, the operators of the technology. The group also recommended that the parameters being monitored by the devices should be permanently recorded from real time collection.

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With respect to the word "permanent" and how it pertained to keeping records, it was suggested and agreed that the data would need to be in a format that could be reviewed and that the medium of the record should be determined by the appropriate regulatory agency.

The responsible regulatory authority determines, in accord with its regulations, the frequency of QC studies. While some states require QC testing as often as every 40 hours of operation, some attendees suggested that QC tests be performed with biological indicators on an annual basis with parametric monitoring to provide confidence in the interim. Alternatively others present expressed the opinion that such yearly QC tests assign too much validity to what some thought were possible variables involved in parametric monitoring. Consequently, no recommendation was made for revalidation intervals for parametric monitors to be included in a STAATTT III guidance report.

Several representatives of regulatory agencies noted that they have neither the personnel nor financial resources to regularly review parametric or biological indicator QC data. Some suggested that as the data are generated electronically, it might be possible to upload the parametric data to transmit it to the regulatory agencies for their review. However, it was noted that the recording and potential uploading would involve proprietary software and/or be site-specific. As such, distant review of electronic data is not currently feasible.

BIOLOGICAL AEROSOLS AND CHEMICAL EFFLUENT

There was consensus that regulators consider as part of their review and evaluation of treatment technologies the following environmental matters:

Environmental Issues

Aerobiology studies of areas adjacent to the treatment equipment/system	Biological and chemical testing of the liquid discharges from the equipment
Balance of air handling through the technology and/or within the area where the equipment is located	QC of environmental factors and equipment use to minimize potential negative environmental impacts from using the treatment equipment
Negative pressure within the system	Fixed portal radiation monitors
Application of HEPA and charcoal filters	

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TEST LABORATORIES

It was the consensus of those attending the conference that laboratories conducting any form of efficacy or validation tests of medical waste treatment technologies be independent of the vendors of these technologies. In addition, the laboratory is responsible for the chain of custody –the preparation of samples, their shipment to the test site, their collection upon completion of testing and their shipment to the laboratory for the analysis of the samples. The review of the test protocols and data generated from the tests are the responsibility of the regulatory agencies.

As a means of minimizing delay and potential rejection of data, it was recommended that laboratories and consultants inform regulators prior to the initiation of testing as to the test protocols and nature of the data that may be generated through the tests. Such involvement of the regulatory agencies could eliminate the need to retest the equipment due to regulatory issues.

EMERGING TREATMENT ISSUES/CONCPETS FOR FURTHER DISCUSSION
BIODEFENSE

Biodefense plans and the disposal of waste generated by bioterrorism events, e.g., 23 reported cases of anthrax spore exposure, are being linked to the use of medical waste technologies. However, these systems were not designed for nor are they intended for use in the treatment of building decontamination residue (BDR) from these sorts of incidents. Given the design of many of these devices and the heat or chemical medium used for treatment, medical waste treatment systems are currently not suitable for use in biodefense. While no recommendations were made, the attendees agreed to reexplore their application at a future date.

TREATMENT OF CHEMOTHERAPEUTICS AND PHARMACEUTICALS

Chemotherapeutics and pharmaceuticals are commonly found in health care facilities and while chemotherapy waste in other than trace amounts is regulated by the EPA through the Resource Conservation and Recovery Act, there is not a similar regulatory body or set of regulations that are concerned with pharmaceuticals entering the waste stream. Since there is concern about the presence of pharmaceuticals appearing in wastewater and other environmental reservoirs, several states already limit or ban the commingling of drug with medical waste.

While some high heat technologies can be expected to deactivate pharmaceuticals, the group did not make any recommendations for the use of alternative treatment technologies in the treatment or disposal of pharmaceuticals. The attendees would welcome additional research and data covering the environmental ramifications of pharmaceuticals in the medical waste stream.

PRIONS

While the most resistant infectious agent to thermal and chemical treatment, the incidents of these forms for disease in humans in the United States is at the most, one per million in the population. Other prion contaminated materials such as waste generated in research with prions, animal carcasses, their body parts or bedding may

present a challenge to facilities attempting to inactivate prion proteins. The attendees did not provide recommendations for the inclusion of these agents in the STAATT III guidance document.

OUTLIERS

As noted earlier in this summary, the STAATT guidance document currently recommends that the efficacy of treatment technologies be determined by subtracting the average colony forming units (CFU) found after treatment from the average CFU recovered from untreated control samples. However, it was suggested that this method may contribute to misleading results and may not allow the assessment of outliers found during studies. To deal with this situation within present procedures for quantitatively assessing results from efficacy studies, it was proposed to set minimum log reduction values in addition to the target average log reductions. For example, the guidance document could present the following goals:

Bacterial spores – required average reduction of 4 $\log_{10}$ **AND** a minimum log reduction of any single test sample of 2 $\log_{10}$

Mycobacterial vegetative cells – required average reduction of 6 $\log_{10}$ **AND** a minimum log reduction of any single test ample of 3 $\log_{10}$

While this approach is similar to that currently in use in the Environmental Protection Agency's *Guide Standard for Testing Microbiological Water Purifiers*, its application in the evaluation of medical waste treatment technologies is not sanctioned by any federal or state regulatory agency. Therefore, this concept, including the minimum log reduction values, needs to be further discussed and evaluated.

NON-MEDICAL WASTE ITEMS

While the STAATT guidance documents address issues related to items commonly defined as medical waste, they fail to consider non-medical waste items that may enter this waste stream. Therefore, future STAATT reports could possibly include responses to one or more of the following questions:

- What common non-medical waste items do generators include in this waste stream?
- Would the inclusion of these items be in violation of state and federal regulations?
- Can these items be effectively processed by medical waste treatment technologies, without creating worker safety issues or damage to the technologies?
- What methods or procedures can be employed to restrict the inclusion of non-medical waste items into the waste stream?
-

It should be note that some states, e.g., California, have amended their medical waste regulations to include definitions and specific handling requirements for items not presently included in the definitions of medical waste. In California, non-RCRA pharmaceutical wastes can be included in the medical waste stream to be incinerated or treated with high heat technologies. General responses to these questions which could be of use to federal and state regulatory agencies will be addressed at subsequent medical waste conferences.

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95% CONFIDENCE INTERVAL CALCULATIONS

The following methods were provided by Mr. Robert McIntrye of the Environment Agency of the United Kingdom:

95% Confidence Intervals for Validation Spore Results

(1) The Control Run

The Control Run utilises either

- A number of spore strips, or
- Sub-samples of waste containing a spore suspension

In both cases the spores samples must be analysed using the methodology that is identical to the test run for the recovery of spores.

The following must be determined

- The mean (X_C) number of spores recovered
- The Log_{10} of (X_C)

For example - From six spores strips the following results are achieved (adjusted to account for analytical dilutions) for number of spores recovered

1.6×10^6
1.3×10^6
1.1×10^6
1.5×10^6
1.2×10^6
1.4×10^6

$$\text{mean } (X_C) = \frac{\Sigma x_C}{N_C} = \frac{8.1 \times 10^6}{6} = 1.35 \times 10^6$$

$Log_{10} (X_C) = 6.13$

Where

- Σx_C Is the sum of the individual results for each spore strips or control samples
- N_C Is the number of spore strips or control samples analysed

(2) D-Value Correction

The D-value is the time taken, in minutes, for a 1 Log_{10} reduction, in the number of spores.

Each batch of spores will have a certified D-value.

Not all batches of spores will have the same D-value. It is accepted that this D-value may vary by up to 100% for commercially available spores of the same type, and that variance beyond this range is available on request.

The choice of spore strip may therefore increase or reduce the number of spores recovered by a factor of 10 and can predictably alter the reported reduction by 2 $\log_{10}$. STAATT considers that in principle 4 log reduction should be demonstrable for **any** commercially available spore batch.

The level III criteria require the use of spores where the certified D-value is $\geq$ 2 minutes

- at 121°C wet heat (*Geobacillus stearothermophilus*)
- at 160°C dry heat (*Bacillus atrophaeus*)

Where certified D-value is < 2 minutes, or determined at parameters other than those identified above, the level III criteria are invalid.

Required Test Reduction

The required Log_{10} reduction can be used to calculate the target test Log_{10} result

Log_{10} (Test) = Log_{10} (X_C) - 4

Using the examples above

Log_{10} (Test) = 6.13 – 4 = 2.13.

Test B: Confidence Intervals for Log Reduction

The test run spores samples must be analysed using the methodology that is identical to the control run for the recovery of spores.

The following must be determined

- The mean (X_T) number of spores recovered
- The standard deviation (σ) of spores recovered
- The Log_{10} of (X_T)
- The Upper 95% confidence interval of (X_T)
- The Log_{10} of the Upper 95% confidence interval of X_T

For example - From six spores strips the following results are achieved (adjusted to account for analytical dilutions) for number of spores recovered

0
167
12
0
15
62

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55
231
0
35

mean (X_T) = $\frac{\Sigma x_T}{N_T} = \frac{641}{10} = 64.1$

Standard Deviation = 81.2

Log mean (X_T) = 1.81

Upper 95% confidence limit (Lu) = mean + (1.96 x Stdev) = 223
The Log of the Upper 95% confidence interval (Log_{10Lu})= 2.35

STAATT Level III CRITERIA

The required log reduction must be achieved with 95% confidence.

(Log_{10Lu}) must be less than Log_{10} (Test)

2.35 is more than 2.13….the required log reduction has not been achieved with 95% confidence

The 95% confidence level of treatment is 6.13 - 2.35 = 3.78

(The mean log inactivation achieved is 6.13 – 1.81 = 4.32)

Routine Monitoring.

Routine Challenge testing may be conducted qualitatively or quantitatively.

Qualitative testing involves the detection of growth/no growth of spores following treatment. The weakness of this method is that the number of spores surviving cannot be determined, and that the frequency of growth occurring is dependent on the input dose, the D-value and the efficacy of the process. This method is recommended for smaller processes, and for processes where the efficacy makes spore growth extremely improbable. Qualitative testing should not be used where growth is expected or has previously occurred.

Quantitative testing involves the enumeration of spores that survive treatment. The advantage is that this allows the efficacy of treatment to be determined. This method is recommended for larger capacity processes and those processes where survival of small number of spores may be a previous of predictable occurrence.

The Assessment of qualitative spore data

Qualitative testing does not permit enumeration of spores. Where growth occurs it is not possible to determine if one, some or all spores survived. All positive results are therefore significant and should be investigated. An individual result may be accepted where parametric monitoring of all critical parameters is in place, is working effectively,

and indicates that the process achieved the required treatment criteria. Where several positive results occur over a period of time this is more significant.

The following criteria are considered to be the minimum standard and best practice should substantially exceed these.

- 95 % of the individual spores strips, with a population of >1 x $10^{4,}$ in the first 6 months of operation , and each calendar year, should demonstrate no growth., AND
- For thermal processes thermal indicator strips should accompany each spore strip and indicate that the minimum time and temperatures have been achieved for 99% of spore strips.
- The number and type of spore/thermal indicator strips used, and the frequency of spore testing throughout the calendar year is uniform.
- For each calendar year a summary report should be prepared that indicates the results obtained and any failures.
- Where >1% (or 1, whichever is greater) of spore strips exhibit growth in any calendar year quantitative testing should be used in future of qualitative.

These criteria must include all test strips recovered from the plant to be valid. The 5% criteria have been provided to allow for both potential contamination and the uncertainty of microbial data.

The Assessment of Quantitative spore criteria

Quantitative testing does permit the enumeration of spores even where growth occurs. The significance of a single positive result can therefore be determined; however consideration should be given to the issues of microbial uncertainty and potential contamination. An individual adverse result may be accepted where parametric monitoring of all critical parameters is in place, is working effectively, and indicates that the process achieved the required treatment criteria. Where several adverse results occur over a period of time this is more significant.

The following criteria are considered to be the minimum standard and best practice should substantially exceed these.

- 95 % of the individual spores strips, with a population of >1 x 10^{6}, in the first 6 months of operation , and each calendar year, should demonstrate 4 $\log_{10}$ inactivation or higher., AND
- For thermal processes thermal indicator strips should accompany each spore strip and indicate that the minimum time and temperatures have been achieved for 99% of spore strips.
- The number and type of spore/thermal indicator strips used, and the frequency of spore testing throughout the calendar year is uniform.
- For each calendar year a summary report should be prepared that indicates the results obtained and any failures. The data should be referenced to the validation report to demonstrate that predicted treatment efficacy, rather than minimum standards, are being achieved. 90% of spore results should demonstrate a level of inactivation ≥ the 95% confidence level of treatment determined during validation.

These criteria must include all test strips recovered from the plant to be valid. The % criteria have been provided to allow for both potential contamination and the uncertainty of microbial data.

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