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UNDERSTANDING & MANAGEMENT OF **EFFICACY TESTING** CRITERIA FOR POTENTIALLY INFECTIOUS MEDICAL WASTE TREATMENT PROCESSES.

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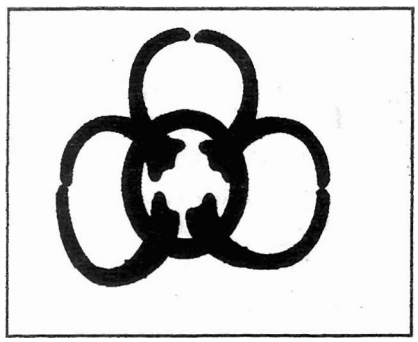

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UNDERSTANDING & MANAGEMENT OF **EFFICACY TESTING** CRITERIA FOR POTENTIALLY INFECTIOUS MEDICAL WASTE TREATMENT PROCESSES.

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INTRODUCTION.

Management of potentially infections Medical Waste (PIMW) is increasingly gaining importance the world over, for maintaining clean Environment and Public Health. Established PIMW treatment technology standards are being upgraded and alternate and Emerging Medical Waste Treatment Technologies are being developed and studied. The consolidation and standardisation on the PIMW subject is very vast and still in its infancy. The work carried out by developed countries such as USA and UK should serve as a basic guideline for all. The hazards of PIMW are widely advocated; and fears of the fall out of Environment pollution caused by Medical Waste Treatment Technology is widely debated and publicised. However, in the process of choosing between the Devil (i.e. PIMW) and the Deep Sea (i.e. Medical Waste Treatment Technologies), the focus is being lost in with regards to the Efficacy Assessment Criteria. This note would guide in understanding of Efficacy Testing Standards & Procedures to Institutional bodies, Alternate and Emerging technology developers and Individuals.

SUMMARY

MEDICAL WASTE TREATMENT TECHNOLOGY EFFICACY ASSESSMENT.

The establishment of specific criteria that define Medical Waste Treatment Efficacy is required to consistently evaluate new or modified medical waste treatment plant operation and technologies. A number of terms are used to denote the level of treatment that may be assigned to a medical waste treatment technology (e.g decontaminate, sterilise, disinfect, render harmless, and kill). However these terms are non-descriptive and do not provide any mechanism for measuring the degree of treatment efficacy. It is critical that terms and performance criteria be established that quantitatively and qualitatively define the level of microbial destruction required of any medical waste treatment process.

Limited number of states in USA have established Efficacy Standards and criteria for Medical Waste Treatment Technologies. This note has used reference from Illinois Environmental Protection Agency(IEPA) title 35 : Environmental protection, chapter 1: Pollution Control Board , Sub chapter b: Potentially Infectious Medical Wastes, Part

:1420, Part :1421, part :1422.[2] The Central Pollution Control Board in India have drafted "Guidelines For Treatment of Hospital Waste by Autoclave", which includes Validation Test, (i.e., the Efficacy test)[3]

It is recommended that all medical waste treatment technologies meet with the following microbial inactivation criteria :

Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a **6 Log_{10}** reduction or greater, and inactivation of *B. stearothermophilus* spores or B. Subtilis spores at a **4 log_{10}** reduction or greater.

In meeting these criteria, selected pathogen surrogates which represent vegetative bacteria, fungi, parasites, Lipophilic / hydrophilic viruses, mycobacteria, and bacteria spores are recommended. Formulas and methods of calculations are recommended and are based on microbial inactivation ("kill") efficacy as equated to "log_{10} kill", which is defined as the difference between the logarithms of the number of viable test micro-organisms before and after treatment.[1]

For better understanding on Microbial Inactivation for its: Definitions; Representatives Biological Indicators: Quantification: and, Efficiency Testing Protocols, refer to the enclosure pages: A-3, A-4, A-5, A-6, and A-7, on state guide line for approval of Medical Waste Treatment technologies.[1]

LEVELS OF MICROBIAL INACTIVATION

Separate classification system has been established to specifically denote levels of microbial inactivation required of Medical Waste Treatment. This classification system would quantitatively and qualitatively define the measure of required performance. Four levels (I, II, III &IV) Microbial Inactivation has been established and this is given in **Table I.**[1]

REPRESENTATIVE BIOLOGICAL INDICATORS.

In the absence of an ultimate pathogen surrogate to represent all defined microbial groups , the selection of pathogen surrogates representing vegetative bacteria, fungi , parasites, viruses, mycobacteria and bacterial spores was considered necessary to Define, Test and approve the Efficacy of the Medical Waste Treatment process. The recommended Biological Indicators are given in **Table II.**[1]

The recommended biological indicator strains selection for treatment technology efficacy testing is given in **Table III.**[1]

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QUANTIFICATION OF MICROBIAL INACTIVATION.

Establishing the mechanism to quantify the level of microbial inactivation is essential in developing the format and requirements of the guidance protocols. Microbial inactivation ("kill") is equated to "Log_{10} kill" which defined earlier, is translated into the following formula:

Log_{10} kill = Log_{10} (CFU/g Introduced) - Log_{10} (CFU/g Recovered)

Where,

Log_{10} kill is equivalent to the term Log_{10} Reduction

"Introduced" is the number of viable test micro-organism recovered after the Medical Waste treatment ; and

"CFU/g" are Colony Forming Units per gram of Medical Waste Solids.

For those Medical Waste treatment process, that can maintain the integrity of the biological indicator carrier (i.e. ampules, plastic strips) of the desired microbiological test strain, commercially available biological indicators of the required strain and concentration can be easily placed, recovered and cultured to demonstrate medical waste treatment process efficacy.

For those Medical Waste Treatment mechanism (shredder, Crusher.) that cannot ensure or provide integrity of the biological indicator carrier, quantitative measurement of efficacy requires two-step approach. This First step, the "control" is typically performed using microbial cultures (i.e. liquid suspensions) of predetermined concentrations necessary to ensure a sufficient microbial recovery at the end of this step. The microbial suspension is added to a standardised surrogate medical waste load that is processed under normal operating conditions without the addition to of the microbial inactivation agent (i.e. heat, chemicals). Standard loads may vary depending on the various treatment challenges (i.e. high moisture content, high organic load, high density) required of the equipment. After processing, waste samples are collected and washed to recover the biological indicator organisms in the sample. Recovered micro-organism suspension are plated to quantify microbial recovery. The number of viable micro-organism recovered serves as a baseline quantity for comparison to the number of recovered micro-organism from wastes proceed with the microbial inactivation agent. The required number of recovered viable indicator micro-organism from the "Control" must be equal to or greater than the number of micro-organism required to demonstrate the prescribed Log reduction as defined in Level III (i.e., a 6 Log_{10} reduction for vegetative micro-organisms and a 4 Log_{10} reduction for vegetative micro-organisms and

a 4 Log_{10} reductions for spores). For further reading refer to enclosure pages A-3 through A-7.

The efficacy of the Waste Residue from Medical Waste Treatment process should be checked.

INITIAL EFFICACY TEST PERIODIC VERIFICATION TESTS MEDICAL WASTE TREATMENT PROCESS.

The manufacture, owner or operator of a Medical Waste Treatment unit should conduct an Initial Efficacy Test, for each model prior to its operation. If significant mechanical changes are made to a treatment unit, the Initial Efficacy Test must be repeated.

Each container of test micro-organisms and/or indicator organism spores is to be placed in the load to simulate the worse case scenario (i.e. that part of the load is most difficult to treat). For example the worst case scenario for an Autoclave would be to place the container of test micro-organism and/or indicator micro-organism spores within a sharps container that must in turn be deposited in a plastic biological bag that is then located centrally within each challenge loads.

Steam Autoclaving of Medical Waste

"Steam autoclaving combines moisture, heat, and pressure to inactivate micro-organisms. This process has been used for sterilizing medical instruments in hospitals for many years and the validation of autoclaving as a sterilization technique for medical equipment is well documented. Test protocols exist for evaluating this application. Steam autoclaving technology also has been used for a long time to treat medical waste. Medical waste may contain many of the same pathogens that are associated with contaminated medical instruments and supplies, **however**, **medical waste probably contains higher levels of organisms in a more complex matrix**. **These differences make it necessary to develop a unique test method specifically for the assessment of steam autoclaving as an effective medical waste treatment technique**".[4] Page 2-1, Clause 2.1

Chemical Antimicrobial Inactivation And Mechanical / Chemical Treatment of Medical Waste

"In the treatment of medical waste, antimicrobial chemicals may be used alone or in combination with a mechanical destructive device such as a shredder or hammermill. The effectiveness of the treatment depends upon the characteristics of the chemical agent, and the characteristics of the waste being treated. At this time no antimicrobial

agent has been registered specifically for medical waste treatment through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) administered by OPTS. Since the AOAC methods for determining the efficacy of antimicrobial agents apply primarily to environmental surfaces, efficacy test methods need to be developed for evaluation of chemical systems used to treat Medical Waste."[4] Page 3-1, Clause 3.1

Microwave Irradiation treatment of Medical Waste.

Microwave treatment of medical waste is an adaptation of an existing technology for a new function. The waste is shredded and sprayed with steam to increase the moisture content to about 10% prior to microwave exposure. This procedure intensifies the heating process by increasing the penetration of the steam into the waste prior to sequential exposure to six microwave units. Since heat and steam are the parameters influencing microbial inactivation, the test method used to evaluate this treatment system was an adaptation of the method used to evaluate autoclave units. However, since the design of the microwave system is substantially different than autoclave that were tested, the protocol was modified to address the specific sampling issues presented by the treatment system. [4] Page 7-5, Clause 7.1.3

Field testing data generated in the evaluation of the commercial medical microwave treatment system showed that microwave irradiation was highly effective in inactivating high levels (10^8) of spores of the mesophillic bacterium *B.subtilis*. That is indicative of a microbial inactivation capability that would readily inactivate viruses, mycobacteria, vegetative bacteria, and yeast and mold spores. The demonstrated inability to inactivate 10^3 of spores of the thermophillic and very heat resistant *B. sterothermophilus* appears to confirm published hypotheses that indicate microwave treatment is based upon thermal inactivation and not on any other intrinsic property of microwave irradiation. The method developed to evaluate the efficiency of microbial inactivation of microwave irradiation medical waste treatment systems could be applied to any such treatment system. Some variations on the sampling procedure may need to be made depending on the design of the particular treatment system. [4] Page 7-5 & 7-6, Clause 7.1.3

CONCLUSION

For Efficacy test of Medical Waste Treatment process, Microbiologist play a vital role in testing and approval prior to disposal of treated waste. The treated waste which is not tested and approved for its efficacy, shall be deemed to be a Potentially Infected Medical Waste, and due precautions shall be taken during handling, storage and disposal as considered for untreated waste.

Based on periodical Efficacy test result given by microbiologists, Medical Waste Treatment Process Equipment operating parameters can be set by the operator / engineer, until the acceptable Efficacy test results are achieved.

No Medical Waste Treatment Process Equipment shall be put to use unless Initial Efficacy tests are carried out.

It is suggested that Medical Waste Management group gives parallel importance to Initial Efficacy test and during in-process Efficacy test.

This note is intended to be thought provoking and directed towards Selection and Management practice for Medical Waste Treatment Process.

TABLE I - LEVELS OF MICROBIAL INACTIVATION [1]

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

TABLE II - RECOMMENDED BIOLOGICAL INDICATORS [1]

Vegetative Bacteria	-	Staphylococcoccus aureus (ATCC 6538) Pseudomonas aeruginosa (ATCC 15442)
Fungi	-	Candida albicans (ATCC 18804) Peicillium chrysogenum (ATCC 24791) Aspergilus niger
Viruses	-	Polio 2, Polio 3 MS-2 Bacteriophage (ATCC 1597-B1)
Parasites	-	Cryptosporidium spp. Oocysts Giardia spp. Cysts
Mycobacteria	-	Mycobacterium terrae Mycobacterium phlei Mycobacterium bovis (BCG) (ATCC 35743)

TABLE III - BIOLOGICAL INDICATOR SELECTION CRITERIA[1]

Vegetative Bacteria - Staphylococcus aureus and Pseudomonas aeruginosa were selected to represent both gram-positive and gram-negative bacteria, respectively. Both are currently required by the Association of Official Analytical Chemists (AOAC) use-dilution meyhod and both have been shown to be resistant to chemical inactivation.

Fungi - The selection of Candida albicans and Penicillium chrysogenum was based on reported data indicating these organisms representing yeast and molds, respectively, are the most resistant to germicides. Although Trichophyton mentagrophytes is the AOAC test organism for molds, Penicillium chrysogenum is reported to be more resistant to germicides. The inclusion of Asperigillus niger as an indicator organism was based on its familiarity as a common mold.

Viruses - Lipophilic (enveloped) viruses are less resistant to both thermal and chemical inactivation than the hydrophilic (noneveloped) viruses. As such, enveloped viruses such as HIV, Herpes simplex virus and Hepatitis B virus are less resistant than enveloped viruses such as Poliovirus, Adenvirus, and Coxsackievirus. Polio 2 (attenuated vaccine strain) and Polio 3 virus were selected based on their relative higher chemical and thermal resistance. Additionally, the use of an enterovirus (e.g., Polio 2 or Polio 3) can provide a stringent measure of efficacy for irradiation treatment processes. MS-2 bacteriophage was selected as a Hepatitis virus surrogate in that this bacteriophage offers a comparable degree of chemical and thermal resistance, is safe to handle and easy to culture.

Parasites - Both Cryptosporidium spp. oocysts and Giardia spp. cysts are used as test organisms to demonstrate germicidal effectiveness. Cryptosporidium has been demonstrated to have a higher chemical resistance and Cryptosporidium spp.oocysts are more readily available than Giardia spp. Cysts. Both are significantly pathogenic (both have an infectious dose of 10 cysts) and care is advised when using these micro-organisms as parasitic biological indicators.

Mycobacteria - Mycobacterium phlei has a demonstrated measure of disinfectant resistance, is a rapid grower and is pigmented for easy identification. M.bovis (BCG) is used in the AOAC Tuberculocidal Method and is analogous to M. tuberculosis in that it is in the same group or complex. Individuals exposed to M. bovis (BCG, ATCC strain) may skin test convert although no actual infectivity or disease occurs. Risk of exposure would come from those mechanisms that grind the waste. Mycobacterium terrae is equivalent to M. tuberculosis in resistance to chemical inactivation. In Europe it is recommended for disinfectant testing. M. terrae does not grow as rapidly as M. bovis or M. tuberculosis.

Bacterial Spores - Both B. stearothermophilus and B. subtilis spores are commonly used as biological indicators for both thermal and chemical resistance. B. stearothermophilus spores exhibit more thermal and chemical resistance than spores from B. subtilis.

REFERANCE

1. Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies, April 1994, USA. A Report of the State and Territorial Association on Alternate Treatment Technologies.- Final document prepared by Nelson S. Slavik, Ph.D., President, Environmental Health Management Systems, Inc.,

2. Illinois Environmental Protection Agency(IEPA) title 35 : Environmental protection, chapter 1: Pollution Control Board , Sub chapter b: Potentially Infectious Medical Wastes, Part :1420, Part :1421, part :1422.

3. "Guidelines For Treatment of Hospital Waste By Autoclave", The Central Pollution Control Board, India.

4. "Evaluation Of Medical Waste Treatment Technologies -Final Report", January 1993, prepared by Research Triangle Institute, prepared for: Work Assignment Leader: Kristina Meson, Office of Solid Waste, U.S. Environmental Protection Agency

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