Biological Waste From Laboratories, An Historical Perspective

John H. Keene, Dr. P.H., RBP, CBSP

Global Biohazard Technologies, Inc

History Of Medical Waste Regulations

- Beach Wash-ups Of Medical Devices In NJ And NY In 1980's
- 1986 EPA Published "EPA Guide To Infectious Waste Management
- 1988 Congress Passed The "Medical Waste Tracking Act Of 1988
- EPA Issues A Report On The Efficacy Of The MWTA

EPA Report

- The EPA Eventually Concluded, That The Disease Causing Potential Of Medical Waste Is Greatest At The Point Of Generation And Naturally Tapers Off After That Point... Thus, Risk To The General Public Of Disease Caused By Exposure To Medical Waste Is Likely To Be Much Lower Than Risk For The Occupationally Exposed Individual

Other Regulations

- OSHA – Bloodborne Pathogens
- DOT – Packaging And Transport Of Medical Wastes
- EPA – Clean Air Act – Control Of Emissions From Medical Waste Incinerators
- State And Local Regulations

Laboratory Biological Wastes

- What Are Laboratory Biological Wastes?
  - Cultures
  - Disposable Equipment Contaminated By Cultures
  - Wastes From Infected Animals
    - Fluids And Tissues
    - Bedding

Reference Document

- **USDA Policies And Procedures On Biohazardous Waste Decontamination, Management, And Quality Controls At Laboratories And Technical Facilities: June, 2009 (ARS document)**

Treatment Methods

- Incineration
  - Animal Carcasses
  - Animal Bedding
  - Infected Tissue
- Chemical Disinfection
    - Liquid Wastes
- Steam Autoclave

Treatment Validation

- Validation Of The Decontamination Process Ensures That Agents Of Potential Harm To Human, Animal Or Plant Health Will Be Killed Or Inactivated Prior To Disposal Or Release Into The Environment.
- Written Procedures Are Needed To Document Process Validation, Provide Proof Of Compliance With Relevant Performance Standards, And Ensure Ongoing Process Performance.
- Each Decontamination Process Should Be Appropriately Validated For The Agent(s) To Be Treated, Regardless Of The Type Of Process.

Incineration

- Pros
  - Complete Destruction
- Cons
  - Permitting
    - Nimbi
  - Maintenance
  - Monitoring

Disinfectants

- Intermediate-level Disinfection Kills Vegetative Microorganisms, Including *Mycobacterium Tuberculosis* And All Fungi, And Inactivates Most Viruses.
- Chemical Germicides Used In This Procedure Often Correspond To Pea-approved "Hospital Disinfectants" That Are Also "Tuberculocidal.".

Disinfectants

- Pros
  - Relatively Easy To Use
  - Considerable Literature Available On Efficacy
- Cons
  - Hazardous Chemicals
  - Non Specific In Action
    - Inactivated By Organic Material
- Follow Manufacturers Directions!!

Autoclaves

- Pros
  - Possible On-site Sterilization
  - Universally Accepted Method
  - Available In Facilities
- Cons
  - Must Be Validated
    - Standard Loads
    - Operation Closely Monitored
  - Mixed Wastes May Be A Problem
  - Possible Release Of Organisms During Vacuum Cycle?

Conditions Of Use

- What Are The Requirements For Sterilization
  - 15 Lbs. Pressure, 15 Minutes, 121^0 C
- Is This Universally Acceptable?
  - No
- What Is Appropriate For Your Situation?
  - It Depends

Autoclave Parameters

- Load Size And Configuration
- Moisture Availability
- Containers
- Time And Temperature

Autoclave

- Biological And Chemical Indicators
- Are They Accurate?
  - What Are You Trying To Prove?
  - When Placed On The Outside Of The Container, They Indicate The Condition Of The Outside Of The Container
  - When Placed In The Container, They Are Difficult To Retrieve And Could Be Contaminated If Process Failed.

Efficacy Evaluation

- Insurance of Effectiveness Includes Monitoring Temperature, Pressure And Cycle Duration Time For Each Cycle And Providing Periodic Decontamination Challenges (Quality Assurance), I.E., Use Of Biological Indicators
- Validation Frequency Should Be Determined By Autoclave Usage And Load Types; Weekly Or Bimonthly For Each Load Type Is Typically Preferred.

QA for Autoclaves

- Quality Assurance For Autoclaves Also Includes:
-
- Ensuring That The Appropriate Containers Are Being Selected For The Waste That Is Being Decontaminated
-
- Ensuring Proper Load Size and Configuration
-
- Providing Personnel Training For The Operation Of An Autoclave

Documentation

- Laboratory/Research Programs That Use A Particular Autoclave Should Maintain A Logbook To Record Autoclave Usage Including:
  - Date Of Treatment
  - Quantity And Type Of Waste Autoclaved
  - Cycle Parameters
  - Name Of Autoclave Operator

Validation

- Prepare A “Standard Load” Of Surrogate Waste
- Determine The Configuration Of The Waste Load
- Place Indicators In Most Difficult Area
- Run Cycles To Determine The Appropriate Time Temperature Relationship For Sterilization

REQUIREMENTS

- Autoclaves Performance Must Be Verified Prior To Initial Use
- Records Must Be Kept Of Each Cycle Run And Procedure Developed For Handling Material From Failed Cycles
- Annual Rechecks/Validation Of Operation Is Required.

Autoclave Myth

- Vacuum Cycles Result In Potential Release Of Infectious Materials
- Research Done By Barbieto And Brookey As Well As Marshall, et. al. Seem To Indicate That Organisms Are Released During The Vacuum Purge Cycles.

Autoclave

- Facts
  - The Research Was Conducted With “Worst Possible Case” Scenario.
  - The Reduction In Numbers Was In The Range Of 10^9
  - The Research Also Demonstrated That Organisms Were Not Pulled Out Of Solution, Or Off Of Surfaces In The Autoclave

Myth Busted

- Under Normal Working Conditions In Biocontainment Laboratories, Autoclaves Do Not Have To Be Equipped With Effluent Decontamination Systems Or Vent Filters.

Conclusions

- Laboratory Medical Waste Treatment Is Subject To State And Local Regulations, But Not Federal Regulation
- Treatment Systems And Transport Of Untreated Waste May Be Subject To Federal Regulation
- Chemical Waste Treatment Is Used For Surface Decontamination And For Liquid Waste Treatment
- Autoclaving Is Still The Most Widely Used And Efficacious Method For Decontamination Of General Laboratory Wastes