Guideline for Approval of Method to Treat Clinical Waste

Introduction

Waste must be managed and disposed of in accordance with the *Protection of the Environment Operations Act 1997* and the *Protection of the Environment Operations (Waste) Regulation 2005.* The Department of Environment, Climate Change and Water (DECCW) is the regulator and administrator of this legislation.

Approval of Method to Treat Clinical Waste

The *Protection of the Environment Operations Act 1997*; Schedule 1 Scheduled Activities - Clause 50 Other definitions, defines clinical waste as follows:

Clinical waste means any waste resulting from medical, nursing, dental, pharmaceutical, skin penetration or other related clinical activity, being waste that has the potential to cause injury, infection or offence, and includes waste containing any of the following:

(a) human tissue (other than hair, teeth and nails),
(b) bulk body fluids or blood,
(c) visibly blood-stained body fluids, materials or equipment,
(d) laboratory specimens or cultures,
(e) animal tissue, carcasses or other waste from animals used for medical research, but does not include any such waste that has been treated by a method approved in writing by the Director-General of the Department of Health.

The effect of the clinical waste definition is to allow the Director-General of the NSW Department of Health to approve, in writing, of any method which may be used to treat clinical waste so that the waste no longer has the properties of clinical waste and can be re-classified for waste regulatory purposes. That is, the waste is no longer injurious, infectious or able to give rise to offence. The approval is separate to any licence which may be issued by DECCW.

The Director-General will not approve of the treatment of any of the following types of waste in the clinical waste treatment stream:

- Cytotoxic waste
- Pharmaceutical waste
- Radiological waste
- Body parts (human tissue, limbs, etc)
- Volatile and semi-volatile organic compounds (including formaldehyde, phenol, and mercury)

Methods of treatment of clinical waste have included sterilisation / disinfection followed by or preceded by shredding. Sterilisation/disinfection methods have included the use of microwave steaming, chemical disinfection and autoclaving.

Other types of waste may be excluded during consideration of the method used to treat clinical waste and depending on the final use of the treated clinical waste. Once clinical waste has been treated according to the approved method it must be re-

classified using the Waste Classification Guidelines issued by DECCW and as in force from time to time.

An approval of a method to treat clinical waste is not generic but related to a specific method using specific apparatus and equipment at specific premises.

Obtaining approval

1. The principal officer or delegate of the company seeking approval must complete the application form “Application for Approval of a Method to Treat Clinical Waste” (Annexure 1) and forward it to the address on the form.

2. The application form must be accompanied by the information specified in Annexure 2.

3. Once the application has been received a request would be made by the Manager, General Environmental Health with a local authorised officer of NSW Health and DECCW to conduct an inspection of the treatment method facility.

4. The application will be assessed in accordance with Annexure 2. During the assessment further information could be requested.

5. Approval will either be granted subject to conditions, similar to those specified in Annexure 3 or approval will be refused. Where approval is refused the reasons for refusal shall be stated.

Annexure 1

The Director
Environmental Health Branch
NSW Health
73 Miller St
North Sydney NSW 2060

Dear Sir

Application for Approval of a Method to Treat Clinical Waste

I / We (person)_____

(Title) _____

of (Registered Business Name) _____

of (Registered Business Address) _____

hereby make application for approval of a "method to treat clinical waste" in accordance with the definition of "clinical waste" in the *Protection of the Environment Operations Act 1997 (Schedule 1)*

Attached in support of this application are the details required in Annexure 2 of the Guidelines for Approval of Method to Treat Clinical Waste.

It is understood that approval of any method to treat clinical waste may be subject to conditions and that the following waste are not permitted to be treated with clinical waste:

- Cytotoxic waste
- Pharmaceutical waste
- Radiological waste
- Body parts (human tissue, limbs, etc)
- Volatile and semi-volatile organic compounds (including formaldehyde, phenol, and mercury)

It is further understood that the Department of Environment, Climate Change and Water must be consulted to determine the classification of the clinical waste once is has been treated by a method approved to treat clinical waste.

Yours sincerely

Signature: .....

Date: ……..

Annexure 2

Information required accompanying an application for an approval of a method to treat clinical waste

1. A description of the clinical waste to be treated and the expected sources of the clinical waste

2. A description of the collection, transport and delivery procedure of the clinical waste

3. A description of the proposed fate of the clinical waste once treated by the approved method

4. A description of the method used to treat the clinical waste accompanied by a process flowchart. The description should include specification of treatment times, temperatures, pressures, chemical concentrations, feed rates, and expected waste load composition

5. Plans and drawings of the layout, devices, apparatus and method of clinical waste treatment

6. Plans of the site and location used to accommodate the method of clinical waste treatment

7. Operational and maintenance manuals including contingency plans for breakdown and trouble-shooting

8. Staff education and training arrangements

9. Details of emission controls for suspected pathological and toxic emissions (if applicable)

10. Occupational health and safety risk assessment and assurance certification

11. Documentation demonstrating microbiological inactivation efficacy using the following biological indicators (not required for incineration):
    i) Mycobacteria (6 Log_{10} reduction)
        * Mycobacterium phlei
        * Mycobacterium bovis (BCG) (ATCC 35743)
    ii) Bacterial Spores (4 Log_{10} reduction)
        * B. stearothermophilus (ATCC 7953)
        * B. subtilus (ATCC 19659)

12. Details are to be provided demonstrating that autoclaves used to treat clinical waste (including microbiological cultures) conform to National Association of Testing Authority (NATA) regulations. To ensure sterility is reached, NATA requires all autoclaves to include a Thermolog strip with each load. Additionally, all load cycles and contents must be recorded and all autoclaves must be calibrated on an annual basis. This includes spatial distribution checks and pressure checks. Validation of the autoclave using biological indicators is to be undertaken on a monthly basis

13. Information about any waste residues including their potential hazards/ toxicities and their mode of disposal

14. Details of any trade waste agreement for liquid waste management

15. Details of Quality Assurance certification by a body accredited by the Joint Accreditation System for Australia and New Zealand (JAS/ANZ)

Annexure 3

Method of Treatment of Clinical Waste
Conditions of Approval that may be Applied

1. APPROVAL

This approval is issued to _____of _____ for the_____ _____ method of clinical waste treatment specified in drawing numbers _____ and manufactured by _____.

2. MARKINGS

All _____ units must be clearly marked with the name and address of the manufacturer _____ and the details of the Australian distributor or agent.

3. INSTALLATION

The _____ may only be installed in a health care facility and only be used by trained facility staff. It must be installed and operated within a properly designed and dedicated waste processing area, separate from patient areas, food storage or preparation areas and clean areas. _____ units are to be installed by qualified tradesperson(s).

4. OPERATION

4.1 The _____ unit must be operated automatically in accordance with the manufacturer's specification.

4.2 Visual and audible alarms must be installed on the waste treatment device to warn the operator whenever any of the parameters are in non-compliance.

4.3 The method of clinical waste treatment must only be used by trained staff.

4.4 The method of clinical waste treatment must mechanically render any sharps unable to puncture the skin.

4.5 The facility should define a standard load and waste configuration for which specific time-temperature parameters have been shown to achieve the microbial inactivation efficacy in accordance with Condition 11. Operators should then monitor waste load sizes, load configurations, waste containment and other conditions that may result in less than optimal heating conditions; whenever these conditions arise, exposure times and steam temperatures should be increased to provide a margin of safety.

4.6 To detect any heating problems, temperature must be monitored continuously during the exposure time and at various points in the chamber.

4.7 A standard cycle with an empty autoclave should be performed annually to detect operational problems.

4.8 Records of time-temperature profiles, maintenance activities and periodic inspections must be kept for a minimum of 5 years.

5. LIQUID WASTE DISPOSAL

All liquid waste must be disposed of in accordance with the local authority requirements. An approval or trade waste agreement is to be sought from the local sewerage authority to dispose of any liquid waste to the sewer.

6. EXCLUDED WASTES

6.1 The _____ unit must not treat the following:

- Cytotoxic waste
- Pharmaceutical waste
- Radiological waste
- Sharps waste
- Human tissue (body parts)
- Volatile and semi-volatile organic compounds (including formaldehyde, phenol, and mercury)

6.2 Wastes audits should be regularly performed to ensure that waste are appropriately segregated to prevent contamination from hazardous chemicals and prohibited waste.

7. PERMITTED CLINICAL WASTE

The _____ unit may treat all components of clinical waste (except body parts) as defined in the NSW Health "Waste Management Guidelines for Health Care Facilities – August 1998"

8. CONTINGENCY PLAN

A contingency plan must be available to all staff to deal with equipment failures.

9. QUALITY ASSURANCE

The _____ device must be manufactured to a Quality Assured Product Standard or the manufacturer has implemented a system of independently audited Quality Assurance certified by a body accredited by the Joint Accreditation System of Australia and New Zealand.

10. MICROBIOLOGICAL TESTING

10.1 The clinical waste treatment system must demonstrate microbiological inactivation efficacy using the following biological indicators:

a) Mycobacteria (6 Log_{10} reduction)
    * Mycobacterium phlei
    * Mycobacterium bovis (BCG) (ATCC 35743)

b) Bacterial Spores (4 Log_{10} reduction)
    * B. stearothermophilus (ATCC 7953)
    * B. subtilus (ATCC 19659)

The samples for evaluation of microbial inactivation must be collected monthly for the first 12 months and on a three monthly basis thereafter. Additional sampling must be undertaken following a change in operation or maintenance.

10.2 All samples for evaluation of microbial inactivation of the treatment process must be submitted to a laboratory accredited by the National Association of Testing Authorities (NATA). Colour-changing chemical indicators or biologicial monitors such as *B. stearothermophilus* or *B.subtilis* spore strips must be placed at the centre of the test load to verify that sufficient steam penetration and exposure time have occurred. The sampling methodology must be documented and the results of all microbiological analysis must be retained and made available upon request by an authorised person. These records must be kept for a period of 5 years.

11. AUTOCLAVES AND RETORTS (STANDARD CONDITIONS)

11.1 Chemical or biological indicators are to be placed in the middle of the waste load to monitor disinfection.

11.2 The autoclave is only permitted to treat laboratory waste, cultures and stock, excluding (chemical waste). Volatile and semi-volatile compounds, bulk chemotherapeutic wastes, mercury, other hazardous chemical wastes, and radiological waste must *not* be treated in an autoclave or retort.

11.3 Waste streams must be properly segregated to prevent hazardous chemicals from being fed into the treatment chamber as toxic contaminants may be released into the air, condensate, or in the treated waste. As poorly segregated waste has the potential to emit low levels of alcohols, phenols, aldehydes, and other organic compounds in the air, independent emission test operating under typical conditions should be conducted to ensure safe conditions.

11.4 Autoclaves and retorts require a minimum exposure time and temperature to achieve proper disinfection. Exposure times are usually based on twice the minimum time required to achieve a 6 $\log_{10}$ kill of bacterial spores under ideal conditions.

11.5 Hazardous odours can be a problem around autoclaves and retorts is there is insufficient ventilation. A mechanical ventilation specialist must certify the adequacy of the ventilation system.

12. ADVANCED AUTOCLAVES

Advanced autoclaves combine steam treatment with pre-vacuuming and/or mechanical processing before, during and after steam disinfection. Shredding or grinding is incorporated into the closed system which is designed to disinfect the air stream prior to release to the environment.

13. AUTOCLAVES (NATA CERTIFICATION)

All autoclaves used to treat clinical waste (including microbiological cultures) are to conform to NATA regulations. To ensure sterility is reached, NATA requires all autoclaves to include a Thermolog strip with each load. Additionally, all load cycles and contents must be recorded and all autoclaves must be calibrated on an annual basis. This includes spatial distribution checks and pressure checks. Validation of the autoclave using biological indicators is to be undertaken on a monthly basis

14. AIR QUALITY

An appropriately qualified mechanical ventilation specialist must be consulted to certify that the treatment room is sufficiently ventilated to prevent a build-up of hazardous fumes and vapours.

15. OCCUPATIONAL HEALTH AND SAFETY

15.1 A risk assessment (in accordance with WorkCover Authority requirements) must be conducted of the waste treatment method/system/facility to ensure compliance with Occupational Health and Safety Requirements.

16. FINAL WASTE CLASSIFICATION

Treated waste must be classified in accordance with the Waste Classification Guidelines issued by the Department of Environment, Climate Change and Water (DECCW) as in force from time to time, before it can be disposed to landfill.

17. APPROVALS

It is recommended that contact be made with the local authority to determine whether any additional approvals are required in relation to the method of treatment of clinical waste.

18. MANUALS

The _____ system must be supplied with education, operation and maintenance manuals which include a troubleshooting section.

19. MICROWAVE SYSTEMS

The microwave clinical waste treatment device needs to be monitored frequently to ensure system performance and prevention of microwave leakage.

20. CHEMICAL-BASED CLINICAL WASTE TREATMENT SYSTEMS

20.1 Chemicals used in the treatment process are hazardous and need to be stored, used and handled with care under appropriate codes.

20.2 The manufacturer of the Clinical Waste Treatment System must provide a risk management plan which will outline potential problems due to hazardous waste contamination. Contingency, staff training and emergency response plans are also required.

21. STAFF TRAINING

Staff must be trained in all aspects of the Clinical Waste Treatment System Standard Operating Procedures, Safety, Maintenance, Shut Down, and Occupational Health and Safety