

Annex 1

Sharps Waste Management Charts of the Surveyed Facilities

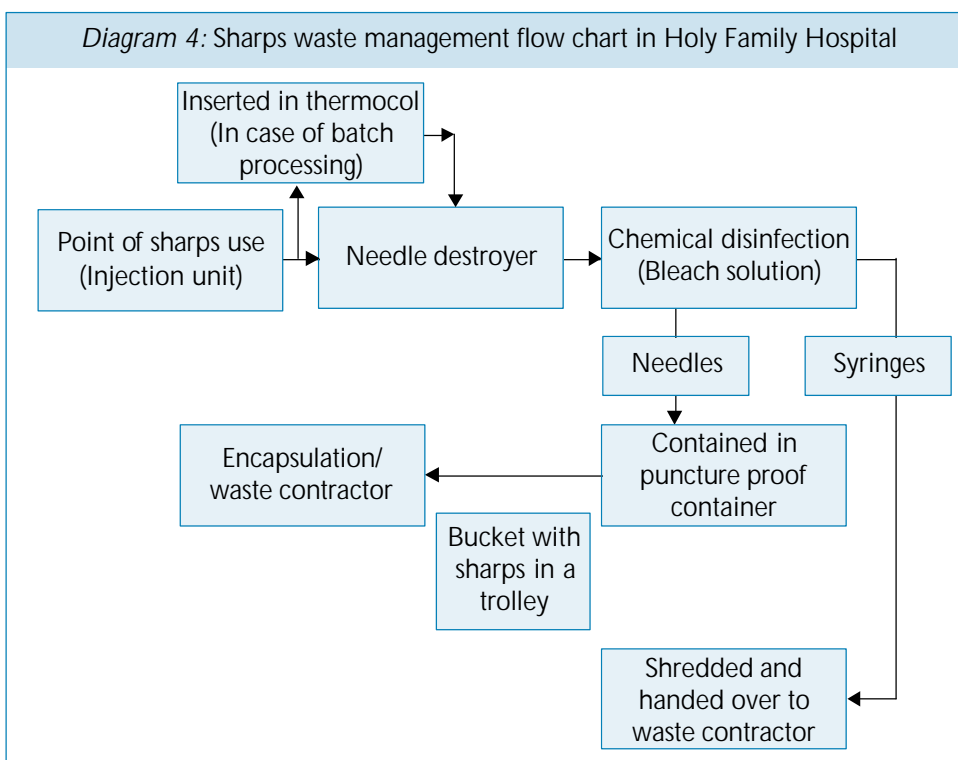
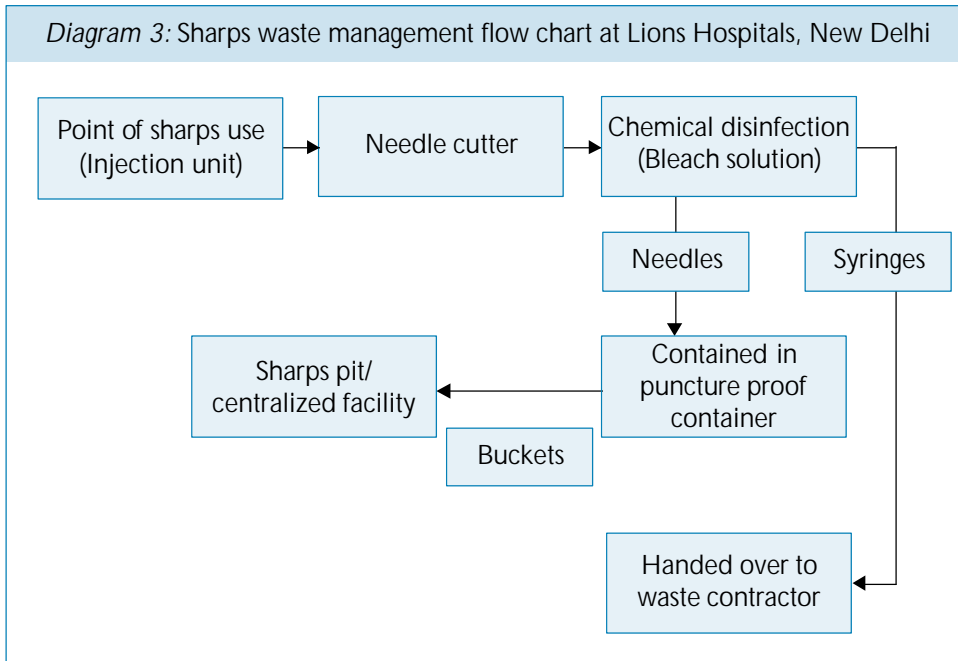


Diagram 5: Sharps waste management flow chart in St. Stephen's Hospital

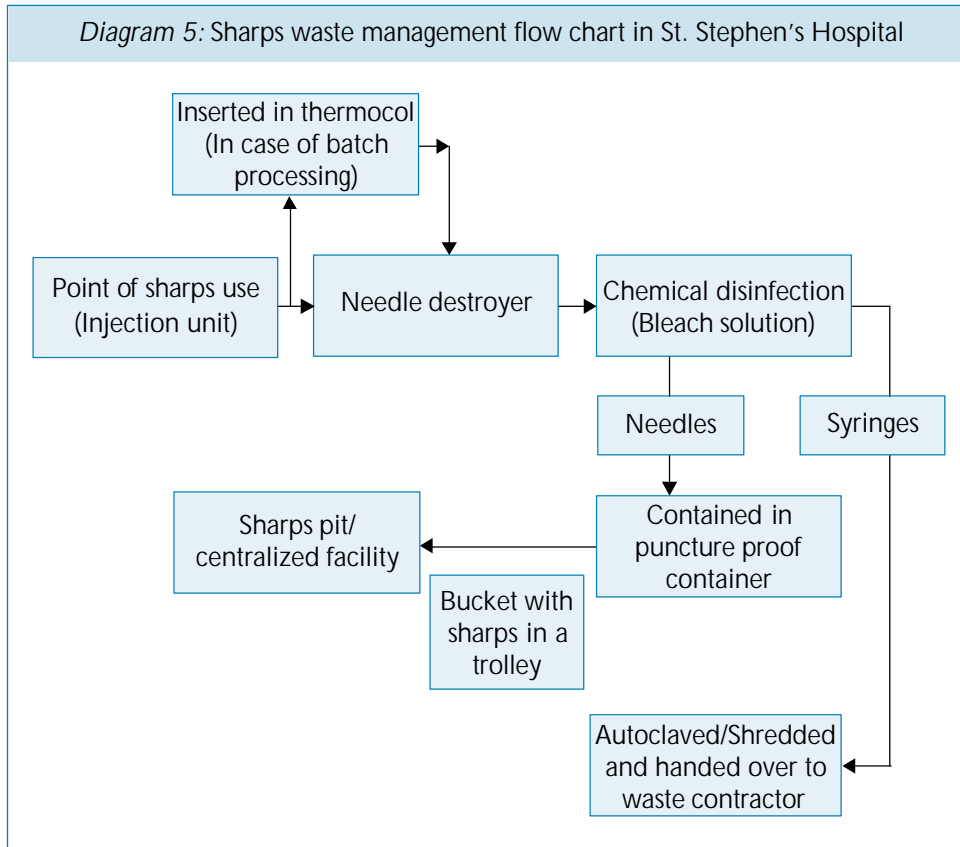


Diagram 6: Sharps waste management flow chart in Ganga Ram Hospital

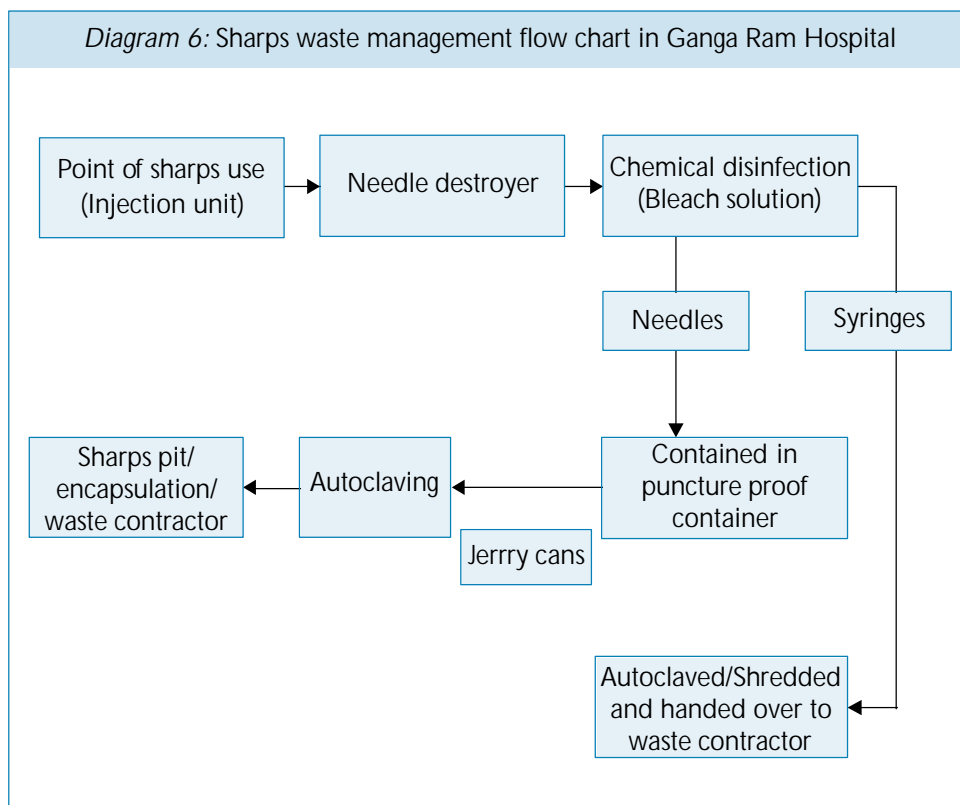


Diagram 7: Sharps waste management flow chart at Dr. Ram Manohar Lohia Hospital

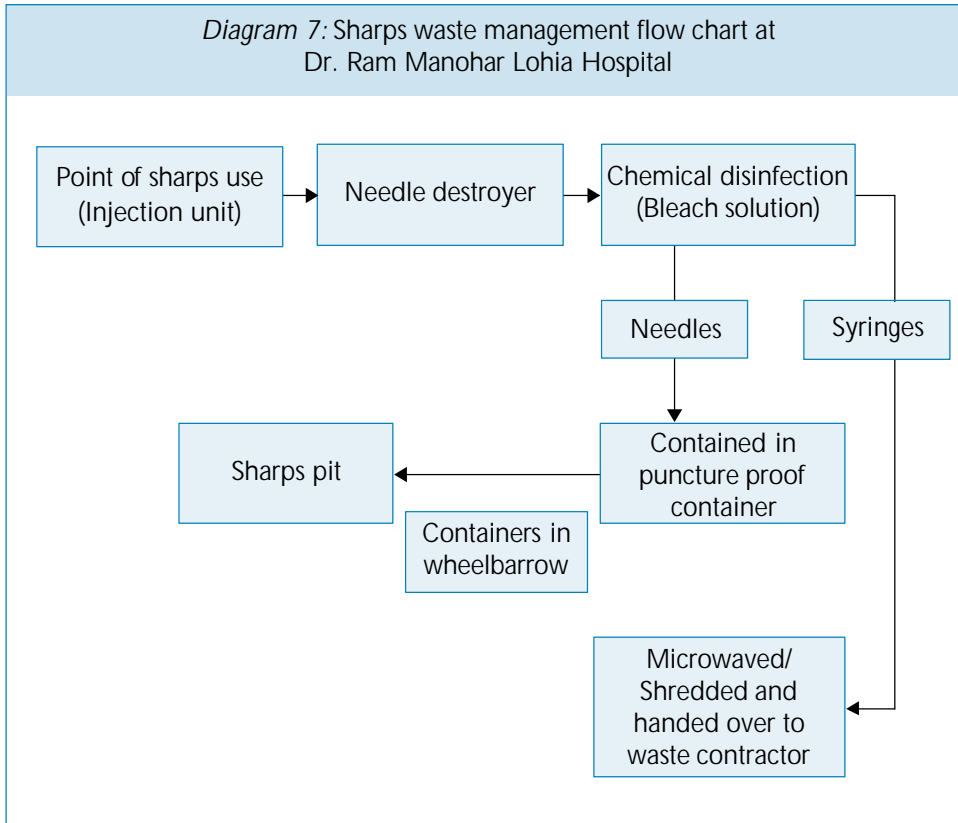


Diagram 8: Sharps waste management flow chart at Ramaiah Medical College

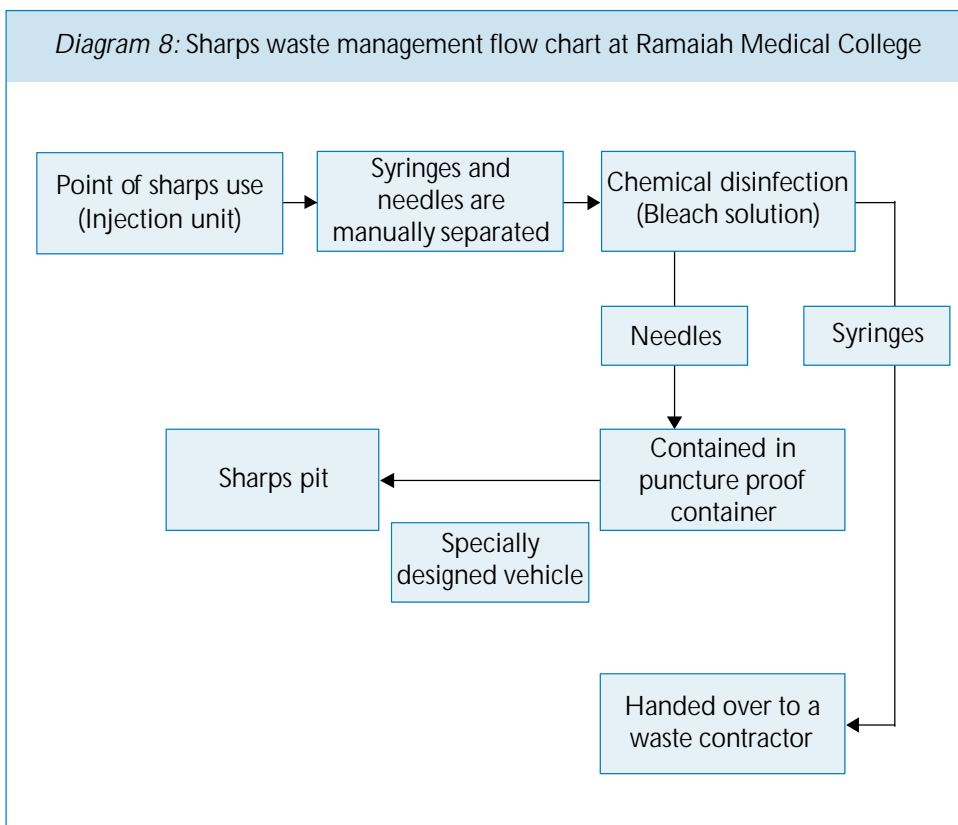


Diagram 9: Sharps waste management flow chart at Air Force Command Hospital

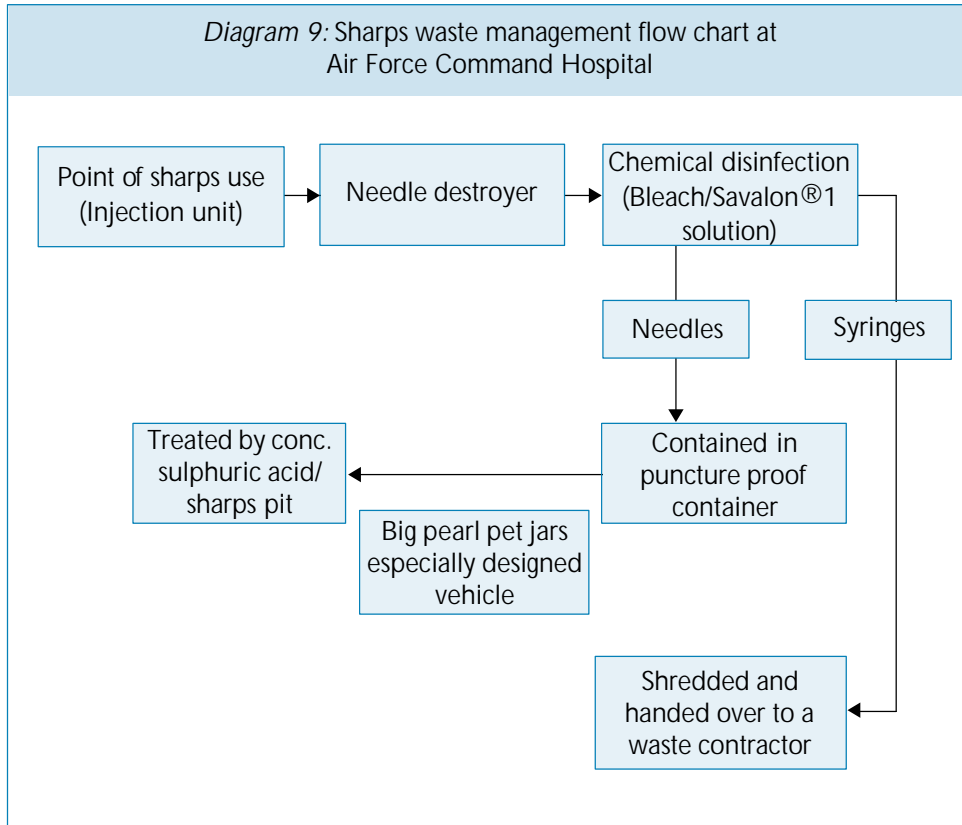


Diagram 10: Sharps waste management flow chart in Sundaram Medical Foundation

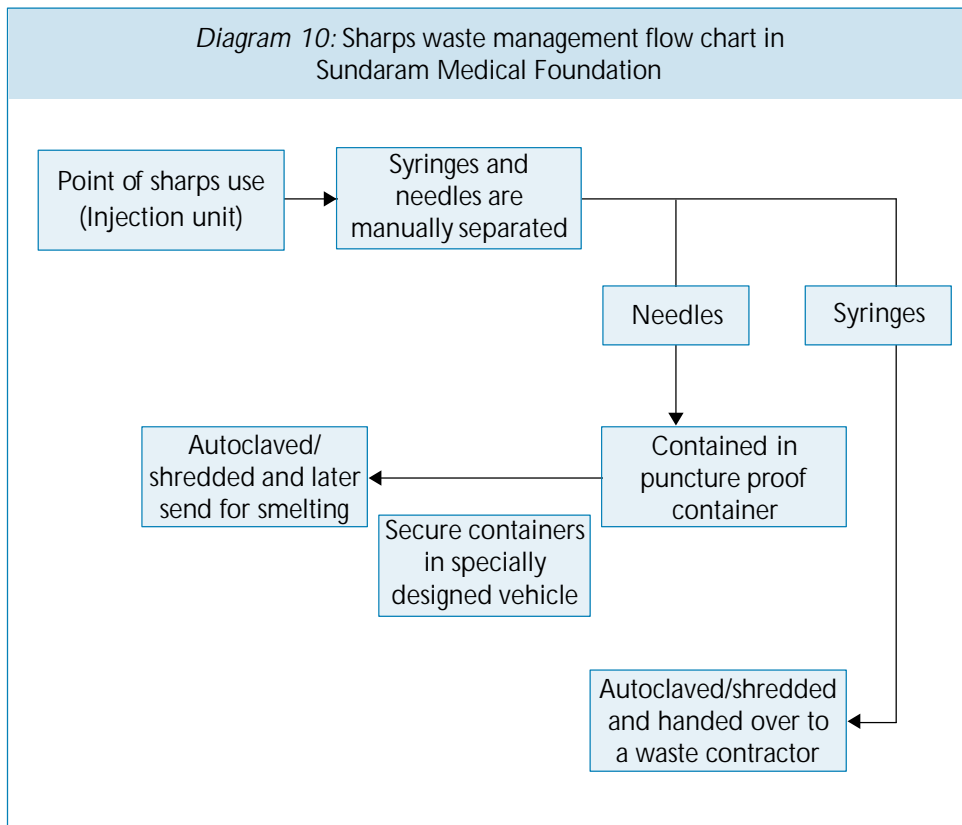


Diagram 11: Sharps waste management flow chart at Tata Memorial Hospital

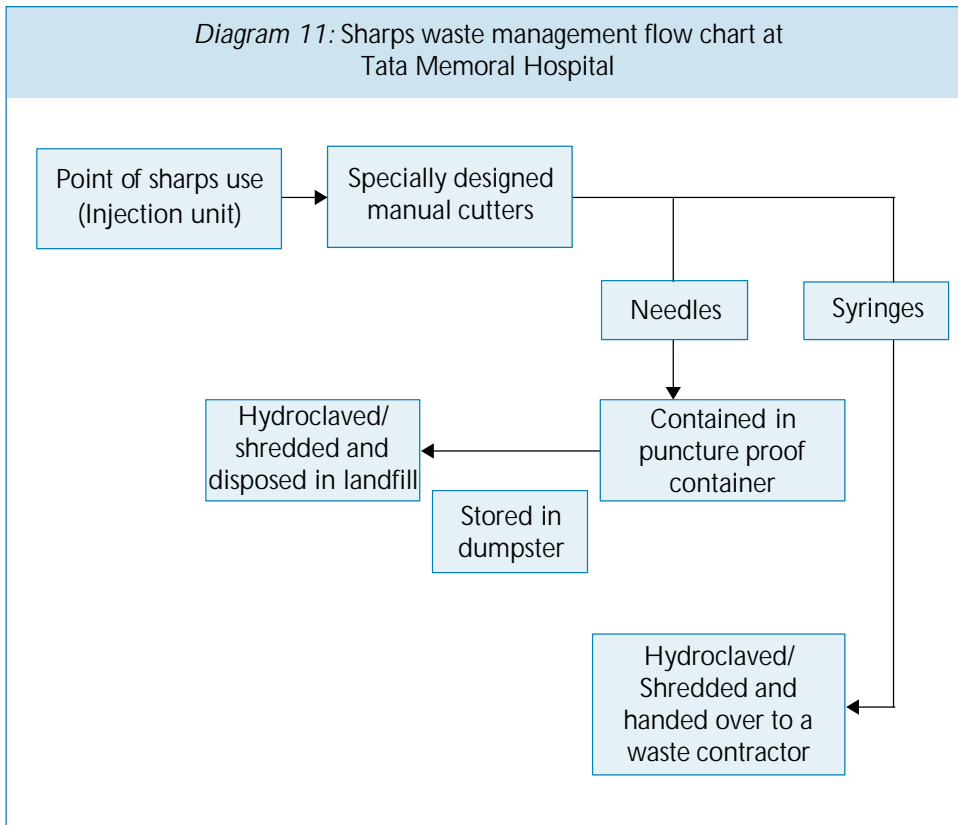


Diagram 12: Sharps waste management flow chart at Medi Care, Hyderabad

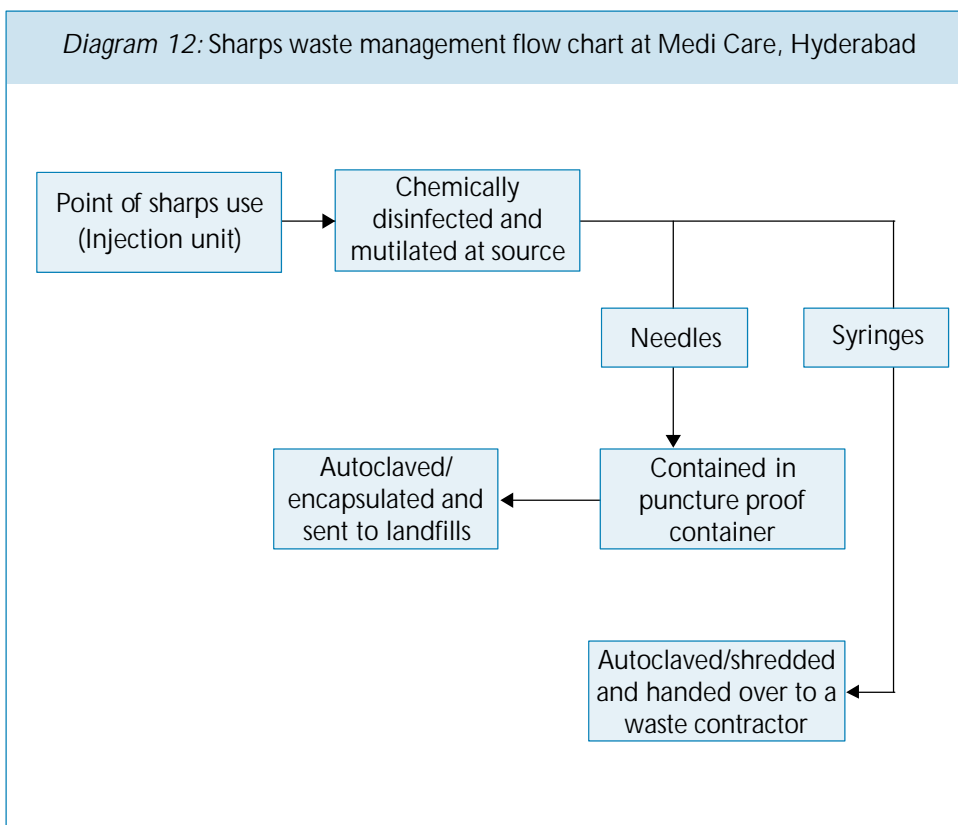


Diagram 13: Sharps waste management flow chart at GJMulticlave, Hyderabad

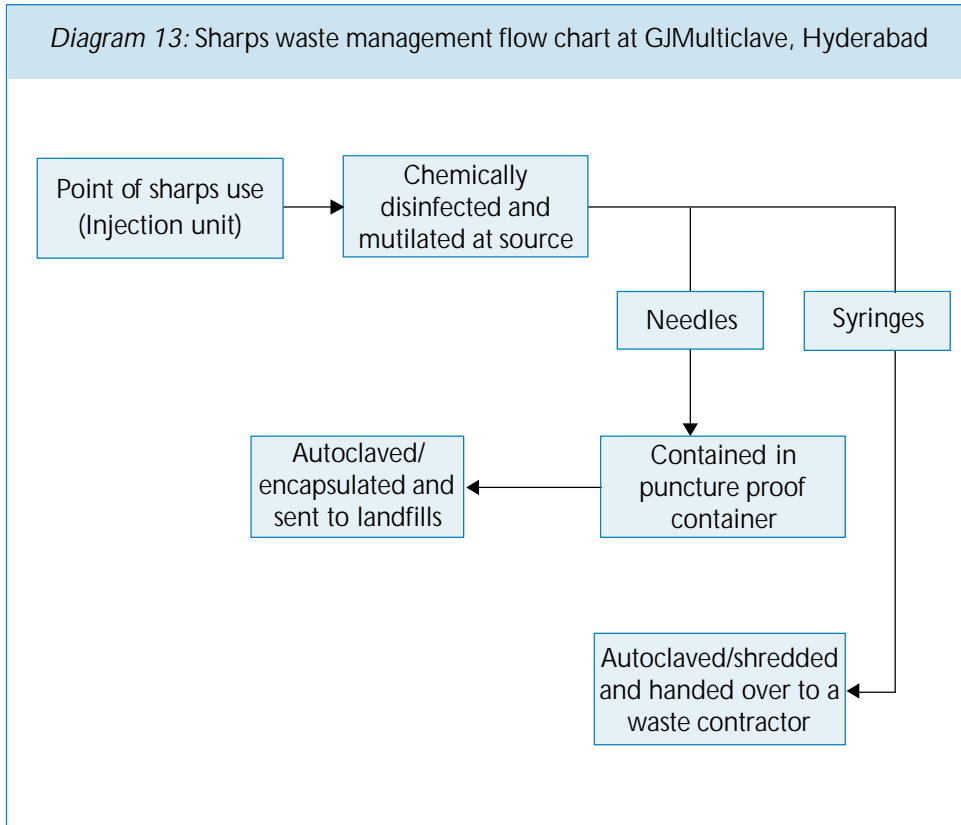


Diagram 14: Sharps waste management flow chart in Sub Divisional District Hospital, Diamond Harbour, Kolkata

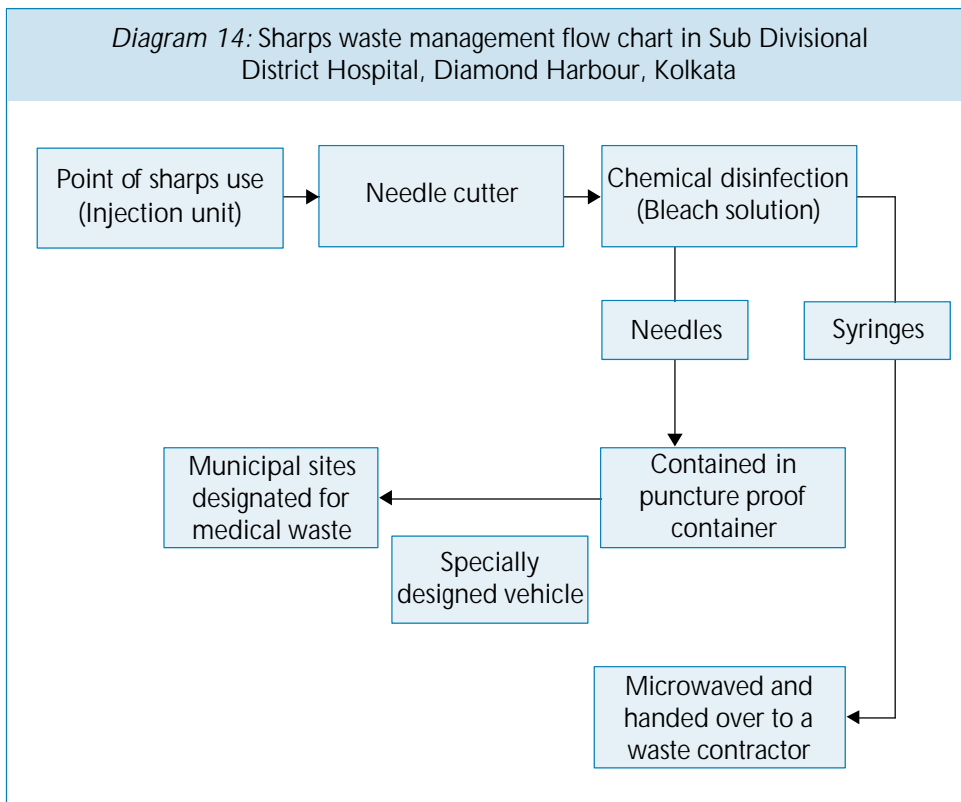
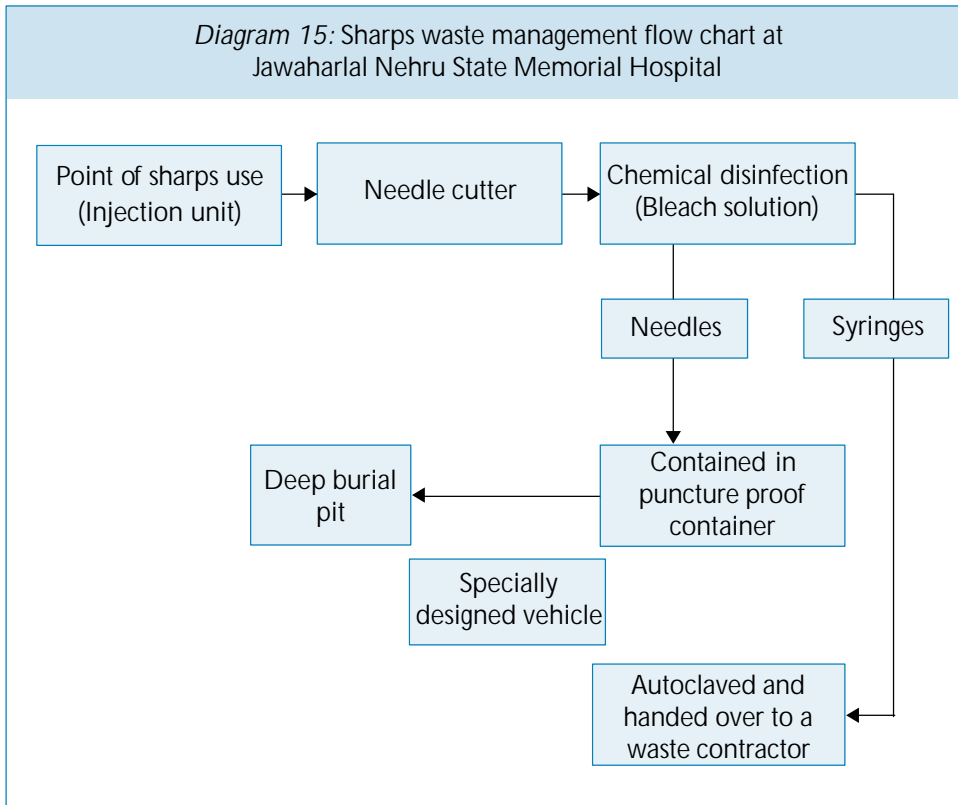


Diagram 15: Sharps waste management flow chart at Jawaharlal Nehru State Memorial Hospital



Annex 2

WHO Health Care Waste Policy, 2005



WORLD HEALTH ORGANIZATION

Safe health-care waste management
POLICY PAPER

1 Unsafe health-care waste management leads to death and disability

Health-care activities lead to the production of waste that may lead to adverse health effects. Most of this waste is not more dangerous than regular household waste. However, some types of health-care waste represent a higher risk to health. These include infectious waste (15% to 25% of total health-care waste) among which are sharps waste (1%), body part waste (1%), chemical or pharmaceutical waste (3%), and radioactive and cytotoxic waste or broken thermometers (less than 1%).

Sharps waste, although produced in small quantities, is highly infectious. Poorly managed, they expose health-care workers, waste handlers and the community to infections. Contaminated needles and syringes represent a particular threat and may be scavenged from waste areas and dump sites and be reused. WHO has estimated that, in 2000, injections with contaminated syringes caused:

- 21 million hepatitis B virus (HBV) infections (32% of all new infections);
- two million hepatitis C virus (HCV) infections (40% of all new infections);
- 260 000 HIV infections (5% of all new infections).

Epidemiological studies indicate that a person who experiences one needle-stick injury from a needle used on an infected source patient has risks of 30%, 1.8%, and 0.3% respectively to become infected with HBV, HCV and HIV. In 2002, the results of a WHO assessment conducted in 22 developing countries showed that the proportion of health-care facilities that do not use proper waste disposal methods ranges from 18% to 64%.

2 Health-care waste management may also represent a risk to health

Health-care waste management options may themselves lead to risks to health and no perfect readily achievable solution to manage health-care waste exists. Health-care waste, whether generated at smaller rural clinics or larger facilities, can be managed where adequate well-operated infrastructures exist. However, the volumes of waste generated within large facilities and targeted public efforts (e.g., immunization campaigns) are more challenging, particularly in developing countries where resources may be limited. In these difficult situations for which waste disposal options are limited, small-scale incinerators have been used and are still used as an interim solution in less developed and transitional countries. However, small-scale incinerators often operate at temperatures below 800 degrees Celsius. This may lead to the production of dioxins, furans or other toxic pollutants as emissions and/or in bottom fly ash. Transport to centralised disposal facilities may also produce hazards to health-care handlers, if not safely managed.

3 Balancing risks to make sound policy decisions in health-care waste management

In addition to risks to health from infectious agents, long-term low-level exposure of humans to dioxins and furans may lead to impairment of the immune system, and impaired development of the nervous system, the endocrine system and the reproductive functions. Short-term high level exposure may result in skin lesions and altered liver function.

The International Agency for Research on Cancer (IARC) classifies dioxins as a “known human carcinogen”. However, most of the evidence documenting the toxicity of dioxins and furans is based upon studies of populations that have been exposed to high concentrations of dioxins either occupationally or through industrial accidents. There is little evidence to determine whether chronic low-level exposure to dioxins and furans causes cancer in humans. Overall, it is not possible to estimate the global burden of diseases from exposure to dioxins and furans because of large areas of uncertainty.

In the last 10 years, the enforcement of stricter emission standards for dioxins and furans by many countries significantly reduced the release of these substances into the environment^[1].

In several Western European countries where tight emissions restrictions were adopted in the late 1980s, dioxin and furan concentrations in many types of food (including breast milk) have decreased sharply.

WHO has established tolerable intake limits for dioxins and furans, but not for emissions. The latter must be set within the national context.

4 Guiding policy principles

In view of the challenge represented by health-care waste and its management, WHO activities are oriented by the following guiding principles:

- Preventing the health risks associated with exposure to health-care waste for both health workers and the public by promoting environmentally sound management policies for health-care waste;
- Supporting global efforts to reduce the amount of noxious emissions released into the atmosphere to reduce disease and defer the onset of global change;
- Supporting the Stockholm Convention on Persistent Organic Pollutants (POPs);
- Supporting the Basel Convention on hazardous and other waste; and
- Reducing the exposure to toxic pollutants associated with the combustion process through the promotion of appropriate practices for high temperature incineration.

5 Strategy

To better understand the problem of health-care waste management, WHO guidance recommends that countries conduct assessments prior to any decision as to which health-care management methods be chosen. Tools are available to assist with the assessment and decision-making process so that appropriate policies lead to the choice of adapted technologies. WHO proposes to work in collaboration with countries through the following strategies:

Short-term:

- Production of all syringe components made of the same plastic to facilitate recycling;
- Selection of PVC-free medical devices;
- Identification and development of recycling options wherever possible (e.g.: for plastic, glass,
- Research and promotion on new technology or alternative to small-scale incineration;

Until countries in transition and developing countries have access to health-care waste management options that are safer to the environment and health, incineration may be an acceptable response when used appropriately. Key elements of appropriate operation of incinerators include effective waste reduction and waste segregation, placing incinerators away from populated areas, satisfactory engineered design, construction following appropriate dimensional plans, proper operation, periodic maintenance, and staff training and management.

Medium-term:

- Further efforts to reduce the number of unnecessary injections to reduce the amount of hazardous health-care waste that needs to be treated;
- Research into the health effect of chronic exposure to low levels of dioxin and furan; and
- Risk assessment to compare the health risks associated with: (1) incineration; and (2) exposure to health-care waste.

Long-term:

- Effective, scaled-up promotion of non-incineration technologies for the final disposal of health-care waste to prevent the disease burden from: (a) unsafe health-care waste management; and (b) exposure to dioxins and furans;
- Support to countries in developing a national guidance manual for sound management of health-care waste;
- Support to countries in the development and implementation of a national plan, policies and legislation on health-care waste;
- Promotion of the principles of environmentally sound management of health-care waste as set out in the Basel Convention; and
- Support to allocate human and financial resources to safely manage health-care waste in countries

Annex 3

Questionnaires Used for this Study

Questionnaire for administrators:

(1) Collect general information about the hospital:

- Name of the hospital
- Type of hospital
- Year of commencement
- Number of beds
- Occupancy rate
- In/ Out Patients
- Other facilities provided
- Catchments area

(2) What is the present waste management system in the hospital?

- Details of the system
- How did the present system develop?
- Any training imparted
- Regular monitoring and record keeping

(3) What is the role of different personnel's involved in the system?

(4) What is the present sharps management system of the hospital?

- At the point of generation, collection and final disposal site.
- Money and Manpower required for the same.
- Any stand by mechanism for managing sharps at each point
- Quantity of sharps generated per day
- Frequency of collection of sharps – everyday / _____ in a week

(5) What are the reasons for choosing the present system?

(6) Do you use a sharps pit for final disposal?

7. If the unit has a sharps pit, what are the dimensions of the pit and where were the specifications derived from?
8. If Yes, How do you transfer the waste into the sharps pit?
9. Is the method safe?
10. Is the pit with a funnel/ pipe?
11. Is any disinfectant added to the pit
12. For how long do you think that this system will last?
13. If no, what are the other methods used? Where do you store the waste before sending the waste for encapsulation or any other final disposal?
14. What was the investment in terms of capital cost and labour?
 - The total investment for sharps management (needle destroyers/ sharps pit)
 - Recurring cost
15. Is this an economically and environmentally viable option?
16. Is the final disposal site located in a secure area?
17. Have there been any incidences of scavenging in the past?
18. Do you think that the present system of sharps management is easy and safe or should a new system be developed?
19. What do you plan to do if the pit gets full?
20. What are the occupational safety measures introduced by the hospital
 - Protective Clothing
 - Immunization
 - Accident reporting
 - Post prophylactic measures
21. Are you satisfied with the present system or will you suggest a different system?
22. With AD syringes being used in immunization programs the volume of medical waste will increase exponentially. How do you suggest handling such large volumes of waste?

23. How would you store the waste before sending for final disposal?
24. Any other comments

Questionnaire for nurses:

1. What is the present waste management system in the hospital?
 - Details of the system
 - Any training imparted
 - Regular monitoring and record keeping
2. What is the role of different personnel's involved in the system?
3. What is the present sharps management system of the hospital?
4. Different categories of sharps generated.
5. How are sharps managed at the point of generation, collection and final disposal site.
6. Method for sharps collection from the patients bed side to the nursing station
 - Are the sharps stored in Puncture proof containers/ bags
 - Is the container closed/ open
 - Any disinfectant used in the container
 - How often is the disinfectant replaced
 - Are the sharps destroyed individual or in bulk
 - If in bulk, why?
7. How are the sharps destroyed?
 - Do you use needle destroyers and cutters
 - Electric/ mechanical
 - How often does the machine gets out of order
 - Any stand by mechanism for managing sharps at the point of generation
 - If manual, what are the methods used?
8. Are you comfortable with the present system?
 - Is it easy to operate the machine
 - Any fine emissions while operating the machine

9. Do you get needle stick injuries?
 - How often do you get one?
 - What are the reasons for it?
 - What is the most common reason for a sharps injury?
 - What are the precautions taken in case of an injury?
10. Occupational safety while handling sharps?
 - Protective gears are provided
 - If yes, are they being used regularly
 - If no, what are the reasons for not using them
11. How is the waste carried from the point of generation to the final disposal site
 - How often are the bins emptied
 - Are the sharps bin emptied regularly or how often?
 - Are the sharps collected manually in open bins/ secure puncture proof containers or polythene bags?
 - What are the precautions taken by them?
12. Do you think that the present system of sharps management is easy and safe or should a new system be developed?

Questionnaire for housekeeping staff:

1. What is your duty in the hospital?
2. What kinds of waste do you collect?
3. Are you aware of the dangers associated with waste specially sharps?
4. Are you aware of the present system of sharps management in the hospital?
5. Does anyone regularly monitor the system?
6. Was any training on waste management imparted?
7. How is the waste treated at the point of generation?
8. What is the collection method from the point of generation?
9. How is the waste carried from the point of generation to the final disposal site

- How often are the bins emptied
 - Are the sharps bin emptied regularly or how often
 - Are the sharps collected manually in open bins/ secure puncture proof containers or polythene bags
 - What are the precautions taken by them
10. Do you get needle stick injuries while handling waste?
 11. How often do you get one and what are the common causes for this?
 12. What do you do if you get an injury?
 13. Do you report about the injury to your seniors?
 14. What precautions do you take while handling waste specially sharps?
 15. Are you vaccinated against Tetanus and Hepatitis B
 16. Do you wear protective gears while handling waste?
 17. Are you comfortable with the present system?
 - Is it easy to operate the machine
 - Any fine emissions while operating the machine
 18. How is the waste carried from the point of generation to the final disposal site?
 19. Do you use a sharps pit for final disposal?
 20. If Yes, How do you transfer the waste into the sharps pit?
 21. Is the method safe?
 22. Is the pit with a funnel/ pipe?
 23. Is any disinfectant added to the pit
 24. If no, what are the other methods used? Where do you store the waste before sending the waste for encapsulation or any other final disposal?
 25. What is the present system of sharps disposal in the hospital
 26. Is the final disposal site located in a secure area?

27. Have there been any incidences of scavenging in the past?
28. Do you think that the present system of sharps management is easy and safe or should a new system be developed?
29. Any other comments

Questionnaire for technology operators:

1. Which technology is used?
2. When was it installed?
3. What is its capacity?
4. Hours of operation of the machine?
5. What kinds of waste are treated?
6. Are sharps also treated by this technology?
7. What is the final residue?
8. How is the residue disposed?
9. What is the environmental pollution control devices installed?
10. Does the technology have the approval of CPCB?
11. What are the occupational hazards associated with the technology?
12. What are the precautions taken by the operators?
 - Years of operation
 - Any injury caused while operating the machine
 - Use of protective gears
 - Immunization
13. What is the operating cost of the machine
 - Manpower
 - Electricity
 - Diesel

- Repair and Maintenance
- Bags / bins used
- Space provided

14. What will be the cost of sending the waste to a centralized facility?

15. Do you think that the present system is satisfactory or will you recommend a new system?

16. Any other comments

Questionnaire for medical officers:

1. Collect general information about the HCI:

- Name of the HCI
- Type of HCI
- Year of commencement
- Number of beds
- Occupancy rate
- In/ Out Patients
- Other facilities provided
- Catchments area

2. What is the present waste management system in the HCI?

- Details of the system
- How did the present system develop?
- Any training imparted
- Regular monitoring and record keeping

3. What is the role of different personnel's involved in the system?

4. What is the present sharps management system of the hospital?

- At the point of generation, collection and final disposal site.
- Money and Manpower required for the same.
- Any stand by mechanism for managing sharps at each point
- Quantity of sharps generated per day
- Frequency of collection of sharps – everyday / _____ in a week

5. What are the reasons for choosing the present system?

6. What was the investment in terms of capital cost and labour?
 - The total investment for sharps management (needle destroyers/ sharps pit)
 - Recurring cost
7. Is this an economically and environmentally viable option?
8. Is the final disposal site located in a secure area?
9. Have there been any incidences of scavenging in the past?
10. Do you think that the present system of sharps management is easy and safe or should a new system be developed?
11. What are the occupational safety measures introduced by the hospital
 - Protective Clothing
 - Immunization
 - Accident reporting
 - Post prophylactic measures
12. Are you satisfied with the present system or will you suggest a different system?
 - With AD syringes being used in immunization programs the volume of medical waste will increase exponentially. How do you suggest handling such large volumes of waste?
13. How would you store the waste before sending for final disposal?

Annex 4

List of Alternative Technology Manufactures and Suppliers

(Note: The designations employed and the presentation of material in this publication do not imply the expression of any opinion or endorsement whatsoever on the part of the Secretariat of the World Health Organization)

Autoclave suppliers

Omron Medical Pvt.Ltd

J-133, R.B Enclave,
Paschim Vihar, New Delhi-110063
Phone. No: 011- 25681536/ 25682541

Samsung Textrade

33/15, Rajpur Road
Civil Lines, New Delhi-110054
Phone No: 011-23944927
Fax No: 011-23926448
Email: Pdhawan_77@hotmail.com

Rockwell Industrial Plants Limited

I-162A/12
Laxmi Nagar, New Delhi-110092
Phone No: 22016961/2/3
Email: ripl@riplindia.com

Medi Aid Technology Services

Nazar Singh place S-19 II Floor
252 Sant Nagar
East of Kailash
New Delhi- 65
Phone No: 011-26405329
Email- medi_delhi@satyamonline.com

Aditya Diagnostics Pvt. Ltd.

(San-I-Pak)
C 5/29 S D A Opp IIT Gate
Outer Ring Road,
New Delhi 110016
Phone .No :011-26527290,
011-26513958
Email: mri@ndf.vsnl.net.in

Machin Fabrik

B 12 Arjun Centra B S D Marg
Govandi Mumbai 400088
Phone No: 022-25555596
Fax No: 022-25560569
Email: machinfabrik@vsnl.com

A W S Clinical Waste

S N G Mercantile Pvt Ltd
4 Ganesh Chandra Avenue
5th Floor Kolkata 700013
Phone No: 033-2373878
Fax No:033-2466856
Email: forsuri@rediffmail.com

Advanced autoclave suppliers

E A M Solution India LTD

FF 30 Avishkar Complex
Old Padra Road Vadodara 390015
Phone No:265-2358869
Fax No: 265-2301474
Email eamsol@sif

Multi Fab (Gujarat) Pvt LTD

403 g I D C Estate,
Makarpura Road
Vadodara 390010
Gujarat
Phone No: 265-2643321
Email – multifab@wilnetonline.net

Jain Hydraulics

10066 Multani Dhanda
1st Floor Street No 1 Paharganj
New Delhi 110055
Phone No: 011-23629689
Email: hewjhpl@ndf.vsnl.net.in

**Consolidated Waste Management
India Pvt.Ltd.**

Cecil Court, M. Bhushan Road
Colaba, Mumbai- 400039
Phone No: 022-2048082
Fax No: 022-2048083
Email: polaris@bom4.vsnl.net.in

Shredded suppliers**Omron Medical Pvt.Ltd**

J-133, R.B Enclave,
Paschim Vihar, New Delhi-110063
Phone. No: 011- 25681536/ 25682541
Fax No: 011-25580964

Health Care Projects (H- PAMCO)

Jhurmut 165, D.D.A., Khirki
Malviya Nagar, New Delhi- 110017
Phone: 011-26210826, 26291828
Email: H-pamco@123india.com

Needle destroyer/cutter manufactures**Mansa-implex**

2 DLF Industrial Area,
Najafgarh Road,
New Delhi-110015
Phone No: 011-25440598

Robonik

31-D, Laxmi Industrial Estate,
Link Road, Anderi(W),
Mumbai- 400053

Penpol

Peninsula Polymers Ltd,
Cabin No.5, Basement-137 Sant Nagar,
East of Kailash, New Delhi- 110065
Phone No:011-26236436

Medi Aid Technology Services

Nazar Singh place S-19 II Floor
252 Sant Nagar
East of Kailash, New Delhi- 65
Phone No:011-26405329
Fax No: 011-26449503
Email: medi_delhi@satyamonline.com

**Health Care Projects and Marketing
Consultancy Organisation (H-
PAMCO)**

Jhurmut 165, D.D.A., Khirki
Malviya Nagar, New Delhi- 110017
Phone: 011-26210826, 26291828
Email: H-pamco@123india.com

Sumukha Power Systems (P) Ltd

No73/35, 5th Cross, Doddanna Ind.
Estate,
Near Peenyaa 2nd Stage,
Bangalore-560091
Phone No: 080-28360160
Fax No: 080-28360690

MEDISYS

Plot P-1, Phase II, Dr. V.S.I Estate,
Thiruvanmiyur, Chennai-41
Phone No:044-24926053
Fax No: 044-24925763
Email- safemax@vsnl.com

M/s Biptronics

H-26A Saket,
New Delhi- 110017
Phone No: 011- 26962032, 26566608
Mobile- 9810009450
soumya@biptronics.com

Emmanuel Technologies

GODFREY A A 1035 3RD cross K N
Extension
Yeshwanthpur Bangalore 560022
Phone No:080- 23474893

Core Health Care,

Core Towers Parimal Crossing,
Ellis Bridge, Ahmedabad

Microwave suppliers

Instromedix (India) Pvt. Ltd.

Pragati Chambers
Ranjit Nagar Commercial Complex
New Delhi- 110008
Phone No: 011-25704965-67
Email: instro@del2.vsnl.net.in

Phone No 011- 26863503, 26868878,
26863236
Fax No: 011- 26868041, 26968517
E mail: promed@vsnl.com

METEKA

Pulse Pharma Pvt Ltd.
208, Ashirwad Commercial Complex
D-1, Green Park, New Delhi- 110016

Technoservice Ecologia

C/o Dr. Massimo Galli
B-2/32, Safdarjung Enclave
New Delhi- 110029
Phone No /Fax No: 011- 26191997

Shredder suppliers

Omron Medical Pvt.Ltd

J-133, R.B Enclave,
Paschim Vihar, New Delhi-110063
Phone. No: 011- 25681536/ 25682541
Fax No: 011-25580964

Health Care Projects (H- PAMCO)

Jhurmut 165, D.D.A., Khirki
Malviya Nagar, New Delhi- 110017
Phone: 011-26210826, 26291828
Email: H-pamco@123india.com

Annex 5

Text excerpts of the Bio-Medical Waste Management and Handling Rules, Second Amendment, 2000, issued by Ministry of Environment and Forests, India

Notification, New Delhi, the 2nd June, 2000

S.O. 630 (E). – Whereas a notification in exercise of the powers conferred by Sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) was published in the Gazette vide S.O. 746 (E) dated 16 October, 1997 inviting objections from the public within 60 days from the date of the publication of the said notification on the Bio-Medical Waste (Management and Handling) Rules, 1998 and whereas all objections received were duly considered..

Now, therefore, in exercise of the powers conferred by section 6, 8 and 25 of the Environment (Protection) Act, 1986 the Central Government hereby notifies the rules for the management and handling of bio-medical waste.

1. Short title and commencement:

- (1) These rules may be called the Bio-Medical Waste (Management and Handling) (Second Amendment) Rules, 2000.
- (2) They shall come into force on the date of their publication in the official Gazette.

2. Application:

These rules apply to all persons who generate, collect, receive, store, transport, treat, dispose, or handle bio-medical waste in any form.

3. Definitions:

In these rules unless the context otherwise requires

- (1) **“Act”** means the Environment (Protection) Act, 1986 (29 of 1986);
- (2) **“Animal House”** means a place where animals are reared/kept for experiments or testing purposes;

- (3) **“Authorisation”** means permission granted by the prescribed authority for the generation, collection, reception, storage, transportation, treatment, disposal and/or any other form of handling of bio-medical waste in accordance with these rules and any guidelines issued by the Central Government.
- (4) **“Authorised person”** means an occupier or operator authorized by the prescribed authority to generate, collect, receive, store, transport, treat, dispose and/or handle bio-medical waste in accordance with these rules and any guidelines issued by the Central Government;
- (5) **“Bio-medical waste”** means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, and including categories mentioned in Schedule I;
- (6) **“Biologicals”** means any preparation made from organisms or micro-organisms or product of metabolism and biochemical reactions intended for use in the diagnosis, immunisation or the treatment of human beings or animals or in research activities pertaining thereto;
- (7) **“Bio-medical waste treatment facility”** means any facility wherein treatment, disposal of bio-medical waste or processes incidental to such treatment or disposal is carried out and includes common treatment facilities;
- (7a) **“Form”** means Form appended to these rules;
- (8) **“Occupier”** in relation to any institution generating bio-medical waste, which includes a hospital, nursing home, clinic dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called, means a person who has control over that institution and/or its premises;
- (9) **“Operator of a bio-medical waste facility”** means a person who owns or controls or operates a facility for the collection, reception, storage, transport, treatment, disposal or any other form of handling of bio-medical waste;
- (10) **“Schedule”** means schedule appended to these rules;

4. Duty of copier:

It shall be the duty of every occupier of an institution generating bio-medical waste which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank by whatever name called to take all steps to ensure that such waste is handled without any adverse effect to human health and the environment.

5. Treatment and disposal

- (1) Bio-medical waste shall be treated and disposed of in accordance with Schedule I, and in compliance with the standards prescribed in Schedule V.
- (2) Every occupier, where required, shall set up in accordance with the time-schedule in Schedule VI, requisite bio-medical waste treatment facilities

like incinerator, autoclave, microwave system for the treatment of waste, or, ensure requisite treatment of waste at a common waste treatment facility or any other waste treatment facility.

6. Segregation, packaging, transportation and storage

- (1) Bio-medical waste shall not be mixed with other wastes.
- (2) Bio-medical waste shall be segregated into containers/bags at the point of generation in accordance with Schedule II prior to its storage, transportation, treatment and disposal. The containers shall be labeled according to Schedule III.
- (3) If a container is transported from the premises where bio-medical waste is generated to any waste treatment facility outside the premises, the container shall, apart from the label prescribed in Schedule III, also carry information prescribed in Schedule IV.
- (4) Notwithstanding anything contained in the Motor Vehicles Act, 1988, or rules there under, untreated biomedical waste shall be transported only in such vehicle as may be authorized for the purpose by the competent authority as specified by the government.
- (5) No untreated bio-medical waste shall be kept stored beyond a period of 48 hours provided that if for any reason it becomes necessary to store the waste beyond such period, the authorized person must take permission of the prescribed authority and take measures to ensure that the waste does not adversely affect human health and the environment.
- (6) The Municipal body of the area shall continue to pick up and transport segregated non bio-medical solid waste generated in hospitals and nursing homes, as well as duly treated bio-medical wastes for disposal at municipal dump site.

7. Prescribed authority

- (1) The prescribed authority for enforcement of the provisions of these rules shall be the State Pollution Control Boards in respect of States and the Pollution Control Committees in respect of the Union territories and all pending cases with a prescribed authority appointed earlier shall stand transferred to the concerned State Pollution Control Board, or as the case may be, the Pollution Control Committees.
- (2) The prescribed authority for the State or Union Territory shall be appointed within one month of the coming into force of these rules.
- (3) The prescribed authority shall function under the supervision and control of the respective Government of the State or Union Territory.
- (4) The prescribed authority shall on receipt of Form 1 make such enquiry as it deems fit and if it is satisfied that the applicant possesses the necessary capacity to handle bio-medical waste in accordance with these rules, grant or renew an authorization as the case may be.

- (5) An authorization shall be granted for a period of three years, including an initial trial period of one year from the date of issue. Thereafter, an application shall be made by the occupier/operator for renewal. All such subsequent authorization shall be for a period of three years. A provisional authorization will be granted for the trial period, to enable the occupier/operator to demonstrate the capacity of the facility.
- (6) The prescribed authority may after giving reasonable opportunity of being heard to the applicant and for reasons thereof to be recorded in writing, refuse to grant or renew authorization.
- (7) Every application for authorization shall be disposed of by the prescribed authority within ninety days from the date of receipt of the application.
- (8) The prescribed authority may cancel or suspend an authorization, if for reasons, to be recorded in writing, the occupier/operator has failed to comply with any provision of the Act or these rules:

Provided that no authorization shall be cancelled or suspended without giving a reasonable opportunity to the occupier/operator of being heard.

8. Authorization

- (1) Every occupier of an institution generating, collecting, receiving, storing, transporting, treating, disposing and/or handling bio-medical waste in any other manner, except such occupier of clinics, dispensaries, pathological laboratories, blood banks providing treatment/service to less than 1000 (one thousand) patients per month, shall make an application in Form 1 to the prescribed authority for grant of authorization.
- (2) Every operator of a bio-medical waste facility shall make an application in Form 1 to the prescribed authority for grant of authorization.
- (3) Every application in Form 1 for grant of authorization shall be accompanied by a fee as may be prescribed by the Government of the State or Union Territory.
- (4) The authorization to operate a facility shall be issued in Form IV, subject to conditions laid therein and such other condition, as the prescribed authority, may consider it necessary.

9. Advisory committee

The Government of every State/Union Territory shall constitute an advisory committee. The committee will include experts in the field of medical and health, animal husbandry and veterinary sciences, environmental management, municipal administration, and any other related department or organization including non-governmental organizations. As and when required, the committee shall advise the Government of the State/Union Territory and the prescribed authority on matters related to the implementation of these rules.

10. Annual report

Every occupier/operator shall submit an annual report to the prescribed authority in Form 11 by 31 January every year, to include information about the categories and quantities of bio-medical wastes handled during the preceding year. The prescribed authority shall send this information in a compiled form to the Central Pollution Control Board by 31 March every year.

11. Maintenance of records

- (1) Every authorised person shall maintain records related to the generation, collection, reception, storage, transportation, treatment, disposal and/or any form of handling of bio-medical waste in accordance with these rules and any guidelines issued.
- (2) All records shall be subject to inspection and verification by the prescribed authority at any time.

12. Accident reporting

When any accident occurs at any institution or facility or any other site where bio-medical waste is handled or during transportation of such waste, the authorised person shall report the accident in Form III to the prescribed authority forthwith.

13. Appeal

Any person aggrieved by an order made by the prescribed authority under these rules may, within thirty days from the date on which the order is communicated to him, prefer an appeal in form V to such authority as the Government of State/ Union Territory may think fit to constitute:

Provided that the authority may entertain the appeal after the expiry of the said period of thirty days if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

14. Common disposal/incineration sites.

Without prejudice to rule 5 of these rules, the Municipal Corporations, Municipal Boards or Urban Local Bodies, as the case may be, shall be responsible for providing suitable common disposal/incineration sites for the biomedical wastes generated in the area under their jurisdiction and in areas outside the jurisdiction of any municipal body, it shall be the responsibility of the occupier generating bio-medical waste/operator of a bio-medical waste treatment facility to arrange for suitable sites individually or in association, so as to comply with the provisions of these rules.

Schedule I: Categories of bio-medical waste (see rule 5)

Waste Category No.	Waste Category Type	Treatment and Disposal Option+
Category No. 1	Human Anatomical Waste(human tissues, organs, body parts)	incineration@/deep burial*
Category No. 2	Animal Waste (animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals colleges, discharge from hospitals, animal houses)	incineration@/deep burial*
Category No 3	Microbiology & Biotechnology Waste (wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biologicals, toxins, dishes and devices used for transfer of cultures)	local autoclaving/micro-waving/incineration@
Category No 4	Waste sharps (needles, syringes, scalpels, blades, glass, etc. that may cause puncture and cuts. This includes both used and unused sharps)	disinfection (chemical treatment@/auto claving/micro-waving and mutilation/shredding
Category No 5	Discarded Medicines and Cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)	incineration@/destruction and drugs disposal in secured landfills
Category No 6	Soiled Waste (Items contaminated with blood, and body fluids including cotton, dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)	incineration/ autoclaving / microwaving
Category No. 7	Solid Waste (wastes generated from disposable items other than the waste sharps such as tubings, catheters, intravenous sets etc).	disinfection by chemical treatment@@ autoclaving/microwaving and mutilation/shredding##
Category No. 8	Liquid Waste (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities)	disinfection by chemical treatment@@ and discharge into drains.
Category No. 9	Incineration Ash (ash from incineration of any bio-medical waste)	disposal in municipal landfill
Category No. 10	Chemical Waste (chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc.)	chemical treatment@@ and discharge into drains for liquids and secured landfill for solids

+ Options given above are based on available technologies. Occupier/operator wishing to use other State-of-the-art technologies shall approach the Central Pollution Control Board to get the standards laid down to enable the prescribed authority to consider grant of authorization

@@ Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfection.

Mutilation/shredding must be such so as to prevent unauthorized reuse.

@ There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated. * Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.

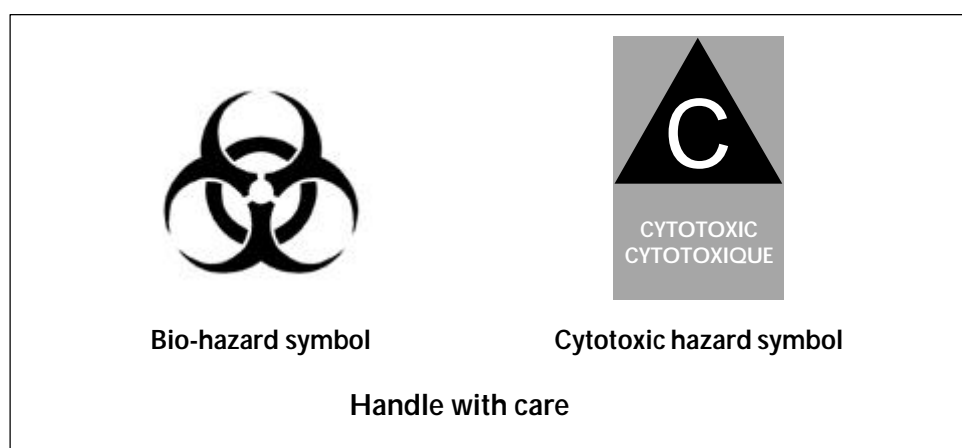
Schedule II: Colour coding and type of container for disposal of bio-medical wastes (see rule 6)

Colour Coding	Type of Container –I Waste Category	Treatment options as per Schedule I
Yellow	Plastic bag Cat. 1, Cat. 2, and Cat. 3, Cat. 6.	Incineration/deep burial
Red	Disinfected container/plastic bag Cat. 3, Cat. 6, Cat.7.	Autoclaving/Microwaving/ Chemical Treatment
Blue/White translucent	Plastic bag/puncture proof Cat. 4, Cat. 7. Container	Autoclaving/Microwaving/ Chemical Treatment and destruction/shredding
Black	Plastic bag Cat. 5 and Cat. 9 and Cat. 10. (solid)	Disposal in secured landfill

Notes:

1. Colour coding of waste categories with multiple treatment options as defined in Schedule I, shall be selected depending on treatment option chosen, which shall be as specified in Schedule I.
2. Waste collection bags for waste types needing incineration shall not be made of chlorinated plastics.
3. Categories 8 and 10 (liquid) do not require containers/bags.
4. Category 3 if disinfected locally need not be put in containers/bags.

Schedule III: Label for bio-medical waste containers/bags (see rule 6)



Note: Label shall be non-washable and prominently visible

Schedule IV: Label for transport of bio-medical waste containers/bags (see rule 6)

	Day	Month
	Year	
	Date of generation	
Waste category No		
Waste class		
Waste description		
Sender's Name & Address		Receiver's Name & Address
Phone No		Phone No
Telex No		Telex No
Fax No		Fax No
Contact Person		Contact Person
In case of emergency please contact		
Name & Address :		
Phone No.		
Note : Label shall be non-washable and prominently visible.		

Schedule V: Standards for treatment and disposal of bio-medical wastes (see rule 5 and schedule 1)

Standards for incinerators:

All incinerators shall meet the following operating and emission standards

A. Operating Standards

(1) Combustion efficiency (CE) shall be at least 99.00%.

(2) The Combustion efficiency is computed as follows:

$$\text{C.E.} = \frac{\% \text{CO}_2}{\% \text{CO}_2 + \% \text{CO}} \times 100$$

(3) The temperature of the primary chamber shall be $800 \pm 50^\circ\text{C}$.

(4) The secondary chamber gas residence time shall be at least I (one) second at $1050 \pm 50^\circ\text{C}$, with minimum 3% oxygen in the stack gas.

B. Emission Standards

Parameters Concentration mg/Nm³ at (12% CO₂ correction)

(1) Particulate matter 150

(2) Nitrogen Oxides 450

- (3) HCL 50
- (4) Minimum stack height shall be 30 metres above ground
- (5) Volatile organic compounds in ash shall not be more than 0.01%

Note :

- Suitably designed pollution control devices should be installed/retrofitted with the incinerator to achieve the above emission limits, if necessary.
- Wastes to be incinerated shall not be chemically treated with any chlorinated disinfectants.
- Chlorinated plastics shall not be incinerated.
- Toxic metals in incineration ash shall be limited within the regulatory quantities as defined under the Hazardous Waste (Management and Handling Rules,) 1989.
- Only low sulphur fuel like L.D.0dLS.H.S.1 Diesel shall be used as fuel in the incinerator.

Standards for waste autoclaving:

The autoclave should be dedicated for the purposes of disinfecting and treating bio-medical waste,

- (1) When operating a gravity flow autoclave, medical waste shall be subjected to :
 - a temperature of not less than 121°C and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes; or
 - a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or
 - a temperature of not less than 149°C and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.
- (2) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of one pre-vacuum pulse to purge the autoclave of all air. The waste shall be subjected to the following:
 - a temperature of not less than 121°C and pressure of 15 psi per an autoclave residence time of not less than 45 minutes; or
 - a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes;
- (3) Medical waste shall not be considered properly treated unless the time, temperature and pressure indicators indicate that the required time, temperature and pressure were reached during the autoclave process. If for any reasons, time temperature or pressure indicator indicates that the required temperature, pressure or residence time was not reached, the entire load of medical waste must be autoclaved again until the proper temperature, pressure and residence time were achieved.

(4) Recording of operational parameters

Each autoclave shall have graphic or computer recording devices which will automatically and continuously monitor and record dates, time of day, load identification number and operating parameters throughout the entire length of the autoclave cycle.

(5) Validation test

Spore testing :

The autoclave should completely and consistently kill the approved biological indicator at the maximum design capacity of each autoclave unit. Biological indicator for autoclave shall be *Bacillus stearothermophilus* spores using vials or spore strips; with at least 1×10^4 spores per millilitre. Under no circumstances will an autoclave have minimum operating parameters less than a residence time of 30 minutes, regardless of temperature and pressure, a temperature less than 121°C or a pressure less than 15 psi.

(6) Routine Test

A chemical indicator strip/tape that changes colour when a certain temperature is reached can be used to verify that a specific temperature has been achieved. It may be necessary to use more than one strip over the waste package at different location to ensure that the inner content of the package has been adequately autoclaved.

Standard for liquid waste:

The effluent generated from the hospital should conform to the following limits

Parameters	Permissible limits
PH	6.3-9.0
Suspended solids	100 mg/l
Oil and grease	10 mg/l
BOD	30 mg/l
COD	250 mg/l
Bio-assay test	90% survival of fish after 96 hours in 100% effluent.

These limits are applicable to those, hospitals which are either connected with sewers without terminal sewage treatment plant or not connected to public sewers. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.

Standards of microwaving

- (1) Microwave treatment shall not be used for cytotoxic, hazardous or radioactive wastes, contaminated animal carcasses, body parts and large metal items.

- (2) The microwave system shall comply with the efficacy test/routine tests and a performance guarantee may be provided by the supplier before operation of the limit.
- (3) The microwave should completely and consistently kill the bacteria and other pathogenic organisms that are ensured by approved biological indicator at the maximum design capacity of each microwave unit. Biological indicators for microwave shall be *Bacillus subtilis* spores using vials or spore strips with at least 1×10^4 spores per milliliter.

Standards of deep burial

- (1) A pit or trench should be dug about 2 metres deep. It should be half filled with waste, then covered with lime within 50 cm of the surface, before filling the rest of the pit with soil.
- (2) It must be ensured that animals do not have any access to burial sites. Covers of galvanised iron/wire meshes may be used.
- (3) On each occasion, when wastes are added to the pit, a layer of 10 cm of soil shall be added to cover the wastes.
- (4) Burial must be performed under close and dedicated supervision.
- (5) The deep burial site should be relatively impermeable and no shallow well should be close to the site.
- (6) The pits should be distant from habitation, and sited so as to ensure that no contamination occurs of any surface water or ground water. The area should not be prone to flooding or erosion.
- (7) The location of the deep burial site will be authorised by the prescribed authority.
- (8) The institution shall maintain a record of all pits for deep burial.

Schedule VI: Schedule for waste treatment facilities like incinerator/autoclave/microwave system (see rule 5)

1.	Hospitals and nursing homes in towns with population of 30 lakhs and above	by 31st December, 1999 or earlier
2.	Hospitals and nursing homes in towns with population of below 30 lakhs,	
	(a) with 500 beds and above	by 31st December, 1999 or earlier
	(b) with 200 beds and above but less than 500 beds	by 31st December, 2000 or earlier
	(c) with 50 beds and above but less than 200 beds	by 31st December, 2001 or earlier
	(d) with less than 50 beds	by 31st December, 2002 or earlier
3.	All other institutions generating bio-medical waste not included in A and B above	by 31st December, 2002 or earlier

Form I: Application for authorization/renewal of authorization (see rule 8)

(To be submitted in duplicate)

To The Prescribed Authority
(Name of the State Govt/UT Administration)
Address.

(1) Particulars of Applicant

- Name of the Applicant
(In block letters & in full)
- Name of the Institution:
Address: Tele No., Fax No. Telex No.

(2) Activity for which authorization is sought:

- Generation
- Collection
- Reception
- Storage
- Transportation
- Treatment
- Disposal
- Any other form of handling

(3) Please state whether applying for fresh authorization or for renewal:
(In case of renewal previous authorization-number and date)

- (4)
- Address of the institution handling bio-medical wastes:
 - Address of the place of the treatment facility:
 - Address of the place of disposal of the waste:

- (5)
- Mode of transportation (in any) of bio-medical waste:
 - Mode(s) of treatment:

(6) Brief description of method of treatment and disposal (attach details):

- (7)
- Category (see Schedule 1) of waste to be handled
 - Quantity of waste (category-wise) to be handled per month

Declaration

I do hereby declare that the statements made and information given above are true to the best of my knowledge and belief and that I have not concealed any information. I do also hereby undertake to provide any further information sought

by the prescribed authority in relation to these rules and to fulfill any conditions stipulated by the prescribed authority.

Date : Signature of the Applicant
Place : Designation of the Applicant

Form II: Annual report (see rule 10)

(To be submitted to the prescribed authority by 31 January every year).

- (1) Particulars of the applicant:
 - Name of the authorized person (occupier/operator):
 - Name of the institution:
Address ,Tel. No , Fax No.
- (2) Categories of waste generated and quantity on a monthly average basis:
- (3) Brief details of the treatment facility:
In case of off-site facility:
 - Name of the operator
 - Name and address of the facility:
Tel. No., Telex No., Fax No.
- (4) Category-wise quantity of waste treated:
- (5) Mode of treatment with details:
- (6) Any other information:
- (7) Certified that the above report is for the period from
Date..... Signature..... Place..... Designation.....

Form III: Accident reporting (see rule 12)

- 1 Date and time of accident:
 - 2 Sequence of events leading to accident
 - 3 The waste involved in accident :
 - 4 Assessment of the effects of the accidents on human health and the environment,.
 - 5 Emergency measures taken
 - 6 Steps taken to alleviate the effects of accidents
 - 7 Steps taken to prevent the recurrence of such an accident
- Date..... Signature..... Place..... Designation.....

Form IV: Authorisation for operating a facility for collection, reception, treatment, storage transport and disposal of biomedical wastes [see Rule 8(4)]

- (1) File number of authorisation and date of issue
- (2)ofis hereby granted an authorisation to operate a facility for collection, reception, storage, transport and disposal of biomedical waste on the premises situated at
- (3) This authorisation shall be in force for a period of Years from the date of issue.
- (4) This authorisation is subject to the conditions stated below and to such other conditions as may be specified in the rules for the being in force under the Environment (Protection) Act, 1986.

Signature.....Date.....

Designation

Terms and conditions of authorisation*

- (1) The authorisation shall comply with the provisions of the Environment (Protection) Act, 1986, and the rules made there under.
- (2) The authorisation or its renewal shall be produced for inspection at the request of an officer authorised by the prescribed authority.
- (3) The person authorised shall not rent, lend, sell, transfer or otherwise transport the biomedical wastes without obtaining prior permission of the prescribed authority.
- (4) Any unauthorised change in personnel, equipment or working conditions as mentioned in the application by the person authorised shall constitute a breach of his authorisation.
- (5) It is the duty of the authorised person to take prior permission of the prescribed authority to close down the facility.

* Additional terms and conditions may be stipulated by the prescribed authority

Form V: Application for filing appeal against order passed by the prescribed authority at district level or regional office of the Pollution Control Board acting as prescribed authority or the State/Union Territory level authority (see Rule 13)

- (1) Name and address of the person applying for appeal:
- (2) Number, date of order and address of the authority which passed the order, against which appeal is being made (certified copy of order to be attached)
- (3) Ground on which the appeal is being made
- (4) List of enclosures other than the order referred in para 2 against which appeal is being filed.

Date..... Signature..... Name & Address.....

Annex 6

Srishti and Medical Waste

WHO we are...

Srishti is an environmental organization dedicated to the improvement of municipal, hazardous and medical waste management. Utilizing community outreach and education, policy analysis and initiatives, research, training and program development, we work at the state and central levels to create solutions for waste management, which are not technology but people driven. Srishti is also involved in a wider range of environmental issues in Delhi as part of a coalition of non-governmental organizations.

WHY we started work on medical waste...

Srishti started work on waste in early '90s and found that untreated infectious waste from the hospitals was reaching municipal dumps. This causes health problems to the ragpickers, municipal workers and the general public exposed to it. Poor hospital waste management takes its toll within the hospitals also. Entire hospital staff is prone to problems related to mismanagement of waste- specifically sharps waste. Improper disposal through incinerators creates additional health hazards; production of cancer-causing dioxins is one of them.

The turning point in all this was the 1996 directive of the Hon'ble Supreme Court of India, according to which all hospitals in Delhi above 50 beds were required to install incinerators. Srishti was instrumental in opposing this polluting and obsolete technology and successfully intervened for the modification of this order and the inclusion of non-polluting alternate technologies and their standards.

WHAT all have we been involved with in medical waste....

- Intervention in the Supreme Court of India case of Dr. B.L. Wadhwa Vs The Union of India for
- Standards for Medical Waste Incinerators
- Inclusion of alternative technologies and their standards
- Implementing waste management schemes in hospitals. (Srishti has set up such systems in 5 hospitals)
- Creating awareness through various seminars, community workshops and training programs.

- Part of the Central Pollution Control Board's (CPCB) 'Peer & Core' group standards committee for Medical Waste technologies
- Srishti is a part of the committee formed under the Director General of Medical Services.
- We have worked with the Ministry of Environment & Forest for the creation of national standards for Bio-Medical Waste.
- Srishti is a member of the Advisory Committee to the Government of Delhi
- We have worked closely with World Health Organization, the World Bank and the United Nations Development Programme in their hospital waste management programmes.
- Our organization actively monitors and documents waste management practices in Delhi

Information dissemination and co-ordination

- Creating and disseminating reports, newsletter and fact sheets on medical waste management
- Organizing and conducting skill shares/ seminars/ workshops
- Working with different PCBs to spread awareness regarding the safe disposal of Bio-medical waste.
- Creating a database of information on medical waste practices.
- Helping building capacity of various organizations/ individuals