

Biomedical Waste Management Rules 2016

Dr. Sanjay Joshi
**Dept of Environmental
Science,**
**K. J. Somaiya College of
Science and Commerce,**
Vidyavihar, Mumbai.
Director, Enviro-Vigil, Thane.
Contact: Mobile: +91-88791

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Healthcare sector in India

- In India, the Healthcare has become one of largest sectors both in terms of revenue and employment. The industry is growing at a tremendous pace owing to its strengthening coverage, services and increasing expenditure by public as well private players
- During 2008-20, the market is expected to record a CAGR (Compound Annual Growth Rate) of 17 per cent.
- Rising income levels, ageing population, growing health awareness and changing attitude towards preventive healthcare is expected to boost healthcare services demand in future
- The low cost of medical services has resulted in a rise in the country's medical tourism, attracting patients from across the world.
- Moreover, India has emerged as a hub for R&D activities for international players due to its relatively low cost of clinical research

Healthcare sector in India

- Growing health awareness and precautionary treatments coupled with improved diagnostics are resulting in an increase in hospitalization
- Indian system of healthcare, Ayurveda has unique therapies which are beneficial for treatment of many chronic lifestyle disorders and thus attracting more number of patients to avail these services in India.

Table indicates the CAGR of hospitalized cases from 2008 – 2016 and has forecast up to 2018

Type of ailment	CAGR (%)
Cardiac	18
Cancer related	16
Diabetes	19

Healthcare sector in India: Environmental Issues

- However, although the healthcare sector in India is growing at an unprecedented rate, with emergence of large number of different types of private and government health care facilities, boosting the Indian economy, these facilities are also generating large amount of highly infectious waste like human anatomical or pathological waste, and also disposable waste materials made up of plastics, glass, rubber etc.
- In addition to these, the veterinary hospitals and colleges and the pharma industries having their own animal houses are also responsible for generation of infectious wastes. A wide variety of drugs including antibiotics, cytotoxic drugs, corrosive chemicals, radioactive substances are also part of the hospital waste
- The advent of disposables in the hospitals has brought in its wake, many illegal practices also. These include inappropriate recycling, unauthorized and illegal re-use and increase in the quantum of waste etc. All round technological progress has led to increased availability of health related consumer goods, which have the propensity for production of increased wastes.

Waste generated from the Healthcare sector in India: Environmental Issues and Legislation

- The issue of improper hospital waste management in India was first highlighted in a writ petition in the Hon'ble Supreme Court; and subsequently, pursuant to the directives of the court, the Ministry of Environment and Forests, (Now MoEF &CC) Govt. of India notified the Bio-Medical Waste (Management and Handling) Rules on 27th July 98; under the provisions of Environmental Protection Act 1986.
- It is defined as any type of waste generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining to the production of drugs in pharmaceutical companies, animal waste generated in the veterinary hospitals and also in the animal houses etc

Biomedical Waste: Nature and composition

- Bio-Medical waste is extremely hazardous, and if not managed properly, can lead to serious health and environment problems.
- Such a waste can also be generated at home if health care is being provided there to a patient.
- Biomedical waste includes pathological, infectious, and hazardous waste such as clinical bandages, gauze, cotton that are contaminated with patients' body fluids, organs and body parts removed during surgery, placenta, dressing materials, aborted fetuses etc.
- From the research labs, stock cultures, blood and blood products, animal carcasses and tissues or organs form highly infectious category of waste.
- Apart from this, needles, scalpels and other metal sharps used in hospitals and research labs get contaminated with body fluids of the patient or animals.

Biomedical Waste: Health and environmental hazard

- This kind of waste is extremely hazardous for the health of all those who get exposed to it quite often. The group of people that are a high risk of getting infection include doctors, nurses, technicians, sweepers, hospital visitors, patients, rag pickers and their relatives etc.
- Apart from the highly infectious waste, the other types of waste such ampoules, chemicals, radioactive wastes, pharmaceutical wastes, pressurized containers, batteries, plastics, low level radioactive wastes, food wastes, and other miscellaneous wastes also form a part of the hospital waste
- Other types of waste include toxic chemicals, cytotoxic drugs, flammable and radioactive wastes. However, over the past nineteen years after the notification of BMW rules, with subsequent amendments, management of biomedical waste in India has become a topic of important concern.



Biomedical Waste: Health and environmental hazard

- As of now several studies on hospital waste have been done. As regards live pathogens found in hospital wastes, the most predominant (80-90%) is the *Bacilli* with *Staphylococci* and *Streptococci* varying between 5 and 10%, whereas the most common pathogens are *Staphylococcus aureus* (from 2-10 colonies per gram of waste)
- *Escherichia coli*, *Pseudomonas aeruginosa* and *Candida albicans* are also common along with varying numbers of other common along with varying numbers of other common nosocomial pathogens such as *Klebsiella*, *Proteus*, *Enterobacter* species.



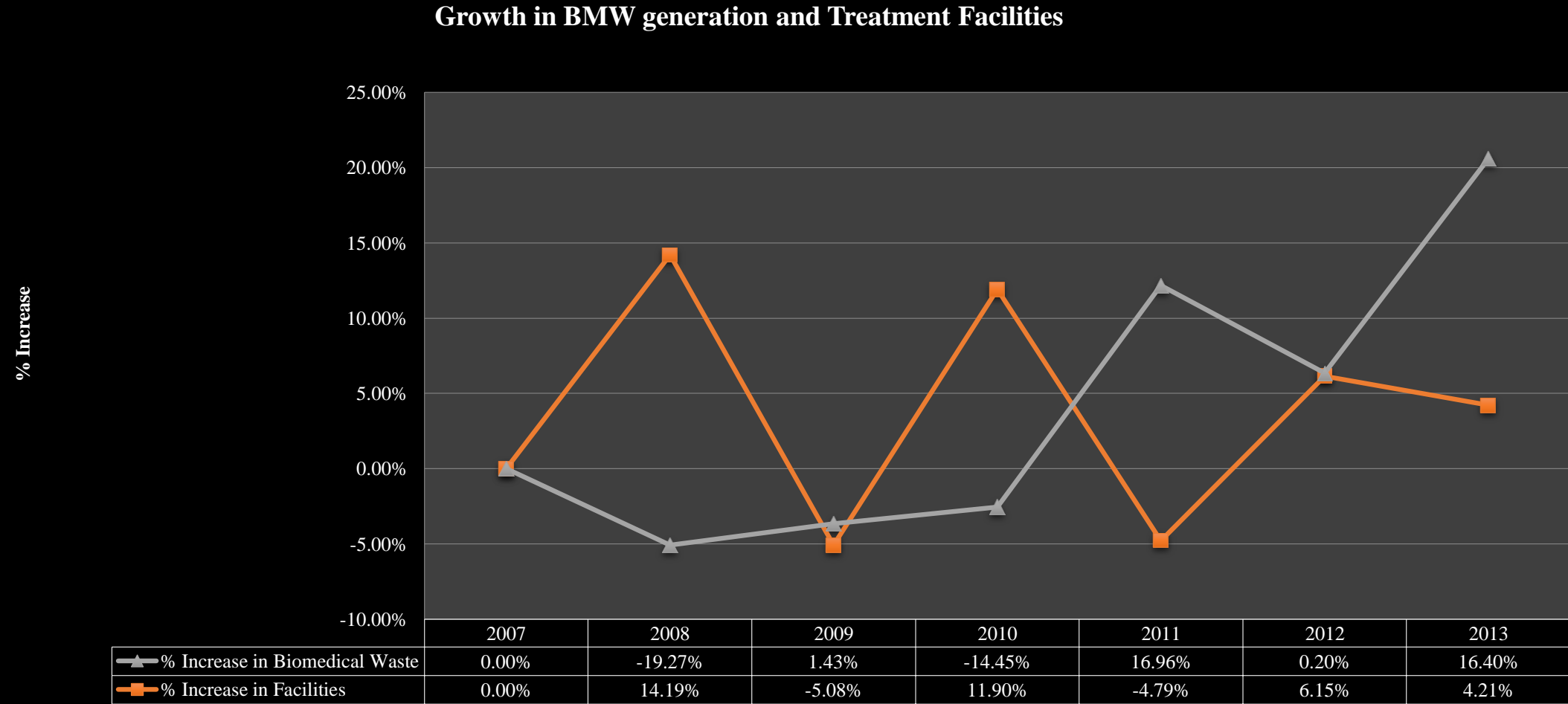
Biomedical Waste: Health and environmental hazard

- The survival rate of viruses has revealed that most material that are present in the in hospital wastes are able to carry viruses keeping them alive for several days (5-8days)
- Bacteria isolated at the soil dumpsite and soil adjacent to dumpsites respectively include *Bacillus* sp (42.86; 45%), *Micrococcus roseus* (14.29 and 10%), *Staphylococcus epidermidis* (9.52 and 10%), *Corynebacterium equi* (1.59 and 5%), *Bacillus subtilis* (4.76 and 5%), *B. licheniformis* (9.52 and 10%), and *Actinomyces israelii* (3.17 and 5%).
- These organisms are associated with various types of human infections.

Biomedical Waste: Health and environmental hazard

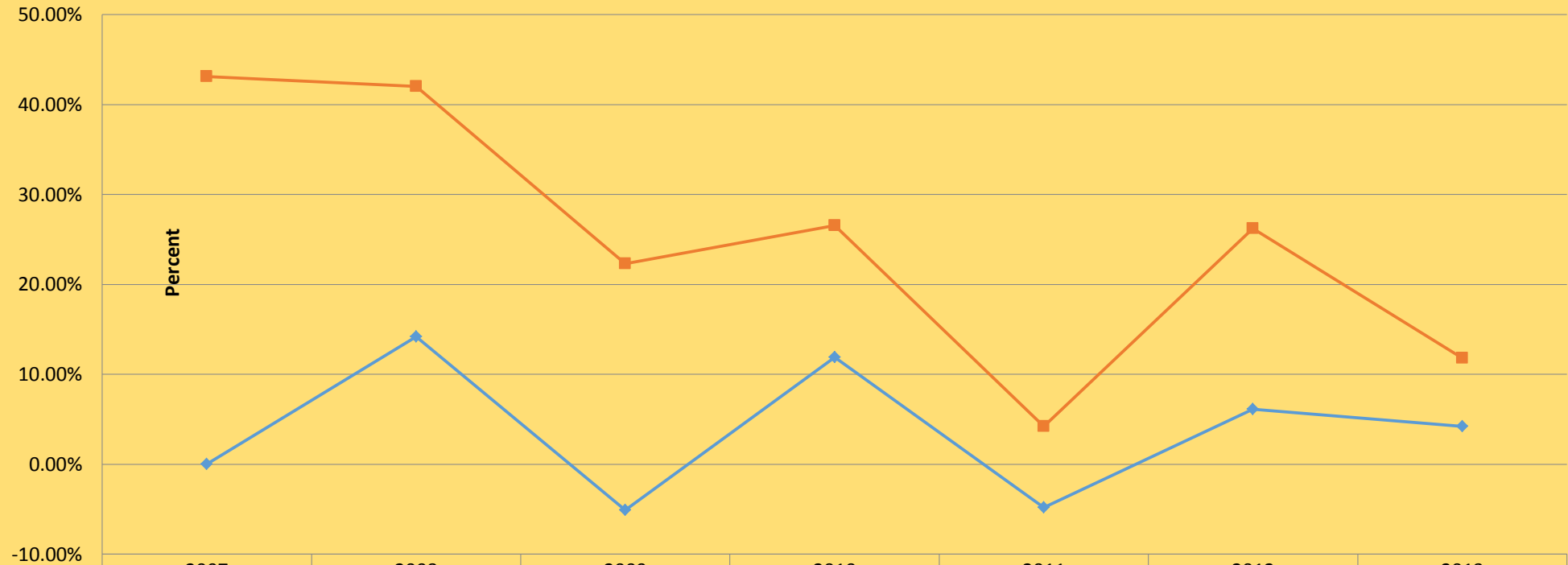
- Healthcare workers belonging to various categories such as doctors, nurses, patients and their relatives, laboratory technicians, housekeeping and sanitary staff and common treatment facility employees are always at high risk of getting infected. Apart from these, rag pickers are also at high risk
- The needle stick injuries are very common among these people
- The health hazards created by improper segregation and lack of precautionary measures include injuries from infectious sharps, exposure to materials like bloody bandages and anatomical wastes and exposure to harmful chemical and radioactive waste
- Infections caused by such exposures are commonly termed Nosocomial or Hospital Acquired Infections and include HIV, Hepatitis A, B and C, Cholera, Typhoid, Dysentery, Staphylococcal infections, Tuberculosis and Candida infections.

Growth in BMW generation and Treatment Facilities



Increase in Facilities Vs % Untreated

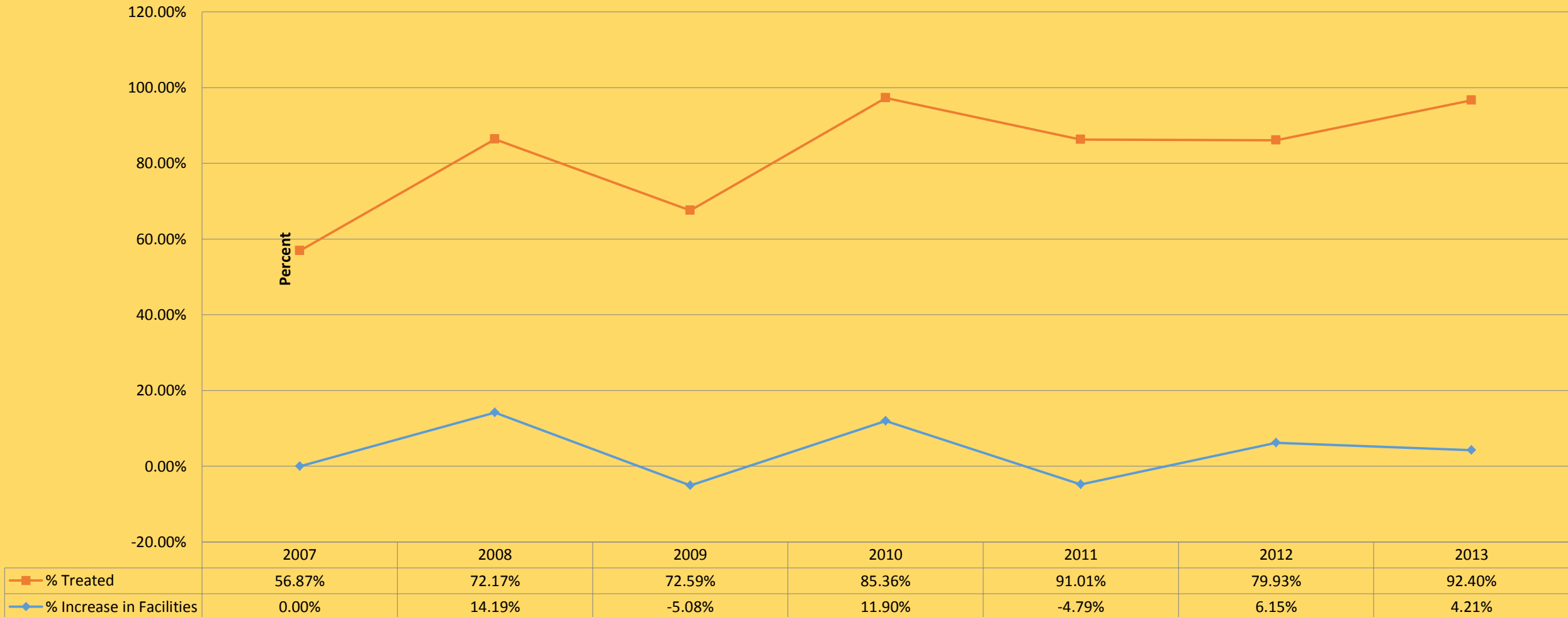
Increase in Facilities Vs % Untreated



% Untreated	43.13%	27.83%	27.41%	14.64%	8.99%	20.07%	7.60%
% Increase in Facilities	0.00%	14.19%	-5.08%	11.90%	-4.79%	6.15%	4.21%

Increase in Facilities Vs % treated

Increase in Facilities Vs % treated



Biomedical Waste : Current Status

- India accounts for 17.5% of the global population and is currently experiencing urban migration rates that are expected to increase another 60% by 2030
- These rates coupled with industrial development and the increased desire for higher standards of living work together to fuel current rates of waste production
- These developments have drastically altered the relationship of millions of people and their local environments and we are only beginning to fully understand what consequences our current waste management methods will have on our future

Biomedical Waste : Current Status

- According to a study conducted by the Indian Institute of Management (IIM) in Lucknow, “Presently 50 to 55 per cent of bio-medical wastes is collected, segregated and treated as per Bio-medical Waste Management Rules.”
- So where is the rest of this waste going? It is dumped in hospital’s backyards, thrown on the side of roads and mixed with municipal garbage
- It has been widely recognized that the first step towards improving biomedical waste management is simply to spread awareness and knowledge about the present situation
- A greater and more widespread understanding of BMW’s potential hazards will help us to reconsider how we perceive waste and further emphasize the importance of public health and environmental issues

Biomedical Waste Management: Legislation

- The original Bio-medical Waste (Management & Handling) Rules of 1998 were comprehensive and stipulated that ‘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 as well as operator of a Common Bio-medical Waste Treatment Facility (CBWTF) to take adequate steps for environmentally sound management of such waste”.
- Also “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 less than 1000 (one thousand) patients per month] shall make an application in Form I to the prescribed authority for grant of authorization”. (ENVIS Newsletter, 2014). These rules were further amended in the year 2000 and 2003 so as to fill the gaps experienced while implementing the BMW Rules.

Biomedical Waste Management: Legislation

- Through the first amendment in the year 2000, the provisions for prescribed authority i.e. State Pollution Control Board (SPCB)/ Pollution Control Committee (PCC) were stipulated for enforcement of the provisions of these Rules in the respective State/UT, Municipal Corporations, Municipalities or Urban & Local Bodies, as the case may be, made 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 (CBWTF) to arrange for suitable sites individually or in association, so as to comply with the provisions of these rules. The Municipal body of the area shall continue to pick up and transport segregated non-bio-medical solid waste as well as duly treated bio-medical wastes for disposal at municipal sanitary landfills.

Biomedical Waste Management: Legislation

- The BMW Rules were further amended in the year 2003, whereby Director General, Armed Forces Medical Services (DGAFMS) notified as Prescribed Authority for enforcement of the BMW Rules by the Health Care Establishments (HCEs) under the Ministry of Defense
- Advisory Committee for implementation of the BMW Rules by the HCEs under the Ministry of Defense is also required to be constituted under the Chairmanship of Additional Director General of Armed Force Medical Services and other members from Ministry of Defense, MoEF, Indian Society of Hospitals Waste Management, Pune. CPCB has a limited role and is required to monitor the implementation of the BMW Rules by the Armed Forces Health Care Establishments under the Ministry of Defense.

Biomedical Waste Management: Legislation

- In the latest amendment in 2016 some new provisions have been incorporated thus increasing the responsibilities of the operators of CBTWF
- These new rules are amended in exercise of the powers conferred by section 6, 8 and 25 of the Environmental (Protection) Act, 1986 (29 of 1986) and in suppression of the Biomedical Waste (Handling and Management) Rules, 1998 except as respects things done or omitted to be done before such suppression, the Central Government, Ministry of Environment, Forests and Climate Change have made these rules which bear short title as the ***Bio-Medical Waste Management Rules, 2016***
- In these rules, in addition to various sources of generation of BMW as mentioned in the original rules of 1998, some new establishments have been added as the sources of generation of the. These are, Ayush hospitals, research or educational institutions, health camps, medical or surgical camps, vaccination and blood donation camps, first aid rooms of the schools and the forensic laboratories and healthcare waste generated at domestic level

- The Ministry of AYUSH was formed on 9th November' 2014
- Earlier it was known as the Department of Indian System of Medicine and Homeopathy (ISM&H) which was created in March 1995 and renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in November 2003
- The intention was to provide focused attention for the development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy.

Biomedical Waste Management: Legislation

- In the original definition of the “Occupier”, there is an addendum, “irrespective of their system of medicine”. It means the family physician of every -pathy is covered and also, the Duties of occupier are described in details
- Laboratory waste, microbiological waste, blood samples and blood bags must be pretreated through disinfection or sterilization on-site in the manner as prescribed by the World Health Organization (WHO) or National AIDs Control Organization (NACO) guidelines and then sent to the common bio-medical waste treatment facility for final disposal
- Establishing the Bar Coding system with GPS to monitor movement of every storage bag from distribution to disposal. Thus it is mandatory for the occupiers to use only those storage bags, that are imprinted with Bar Codes
- Chlorinated plastic bags used for collection, treatment and disposal should be phased out within 2 years and replaced with non-chlorinated bags

Biomedical Waste Management: Legislation

- Duties of the operator of a common biomedical waste treatment and disposal facility are newly introduced
- Record of Recyclable BMW should be maintained and should be made available to SPCB
- If application of Authorization remains as pending with the authorities for more than 90 days, applicant should presume that the facility has got the authorization (conditions apply)
- Local self-government is liable to provide adequate land for common BMW facility.
- Cytotoxic drugs should be returned back to the manufacturer or send for incineration at temperature $>1200^{\circ}\text{C}$

Biomedical Waste Management: Legislation

- Glassware & Metallic Body Implants, broken or discarded glass should be stored in Cardboard Boxes with Blue Coloured marking instead of Plastic Bag.
- Dead Foetus should be considered as Anatomical waste.
- Bio-medical waste generated in households during healthcare activities shall be segregated and should be handed over to CBMWT SDF.
- Secondary chamber gas residence time shall be at least 2 seconds.

BMW Legislation: Duties of Operators

As mentioned in the amended rules, it shall be the duty of every **operator** to –

- Take all necessary steps to ensure that the bio-medical waste collected from the occupier is transported, handled, stored, treated and disposed of, without any adverse effect to the human health and the environment, in accordance with these rules and guidelines issued by the Central Government or, as the case may be, the central pollution control board from time to time
- Ensure timely collection of bio-medical waste from the occupier as prescribed under these rules

BMW Legislation: Duties of Operators

- Establish bar coding and global positioning system for handling of bio-medical waste within one year.
- Inform the prescribed authority immediately regarding the occupiers which are not handing over the segregated bio-medical waste in accordance with these rules;
- Provide training for all its workers involved in handling of bio-medical waste at the time of induction and at least once a year thereafter
- Assist the occupier in training conducted by them for bio-medical waste management;

BMW Legislation: Duties of Operators

- Undertake appropriate medical examination at the time of induction and at least once in a year and immunize all its workers involved in handling of bio-medical waste for protection against diseases, including Hepatitis B and Tetanus, that are likely to be transmitted while handling bio-medical waste and maintain the records for the same
- Ensure occupational safety of all its workers involved in handling of bio-medical waste by providing appropriate and adequate personal protective equipment

BMW Legislation: Duties of Operators

- Report major accidents including accidents caused by fire hazards, blasts during handling of biomedical waste and the remedial action taken and the records relevant thereto, (including nil report) in specific format to the prescribed authority and also along with the annual report
- Allow occupier, who are giving waste for treatment to the operator, to see whether the treatment is carried out as per the rules.
- Shall display details of authorization, treatment, annual report etc on its web-site.

BMW Legislation: Duties of Operators

- After ensuring treatment by autoclaving or microwaving followed by mutilation or shredding, whichever is applicable, the recyclables from the treated bio-medical wastes such as plastics and glass, shall be given to recyclers having valid consent or authorization or registration from the respective State Pollution Control Board or Pollution Control Committee
- Supply non-chlorinated plastic coloured bags to the occupier on chargeable basis, if required.
- Common bio-medical waste treatment facility shall ensure collection of biomedical waste on holidays also;
- Maintain all record for operation of incineration, hydro- or autoclaving for a period of five years; and
- Upgrade existing incinerators to achieve the standards for retention time in secondary chamber and Dioxin and Furans within two years from the date of this notification.

Thank You