Chapter 2

INTERNATIONAL LEGAL MECHANISMS

2.1 Introduction

International law derives from a number of sources, principally international conventions or treaties, international customary law and the general principles of law recognized by States. In recent years, all of these sources have displayed features of interest to international environmental law. The inherent reservation notwithstanding, treaties and conventions have made a major contribution to developing international environmental law over the last few years. In order to achieve sustainable development, it is imperative to address on priority basis the principal social economic and environmental changes contained in Agenda 21. The number 21 refers to an agenda for the 21st century. It also refers to the number on the UN's agenda at this particular summit.
specific in nature, concluded at different times with uneven international knowledge and concern.

The earth’s atmosphere is a common heritage. The environmental issues take into account the human being and not the State as a unit. It is therefore a global issue. Even though the United Nations has convened an International Conference on the Human Environment at Stockholm 1972, where a dialogue on protection of environment had begun and despite the fact that later the United Nations Environment Programme (UNEP) was established and subsequently the concepts of sustainable development and development without destruction evolved, Bio-Medical Waste Management concerns did not come on the agenda and did not take centre stage. However, the Stockholm declaration recognized that Man is a part of nature and his life depends on it. The Secretary General, United Nations in Stockholm Conference appealed for a joint and concerted effort by all on this planet. At the said Stockholm Conference the world reiterated that it is the duty of every person to protect the environment and prevent its pollution and since then, domestic laws and international treaties impose this duty on individuals and even states.

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60 Also known as the Stockholm Conference was an international conference convened under United Nations auspices held in Stockholm, Sweden from June 5-16, 1972. It was the UN's first major conference on international environmental issues, and marked a turning point in the development of international environmental politics.

61 The United Nations Environment Programme coordinates United Nations environmental activities, assisting developing countries in implementing environmentally sound policies and practices. It was founded as a result of the United Nations Conference on the Human Environment in June 1972 and has its headquarters in Nairobi, Kenya. UNEP also has six regional offices and various country offices.

62 U. Thant said “Like it or not we are travelling together on a common planet and we have no national alternative in which we and our children can live a full and peaceful life.”
Few countries of the world have specific legislation to deal with the management and handling of Bio-Medical Wastes. The study has revealed information about the legal mechanisms prevalent in the United States of America, United Kingdom, Australia, South Africa, Europe, Asian and South Asian countries, all of which have legislative enactments of different types to deal with Bio-Medical Waste Management.

The International Community recognised this responsibility and drafted several instruments reminding Man to be kind to the natural world. After the loss of millions of human beings the UN Charter expressed a deep concern for the people yet to be born.63 Likewise, the Right to a healthy world was also reiterated at the Stockholm conference in 197264 that explained the imperative goal for mankind so as to defend and improve the human environment for present and future generations. Besides war, peace and development, the International Law made a beginning in regulating the environmental issues. It was felt that mankind has both a right to a healthy world around and a solemn responsibility to protect and improve the environs for the next generation.

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63 Preamble to the Charter of the United Nations Organisation, 1945
64 Supra note 60 at p. 33
The United Nations and the World Health Organisation took forward the theme, by adopting the World Charter for Nature in 1982, which explicitly states that Governments have a duty to pass on their natural heritage to future generations. The WHO regional office for Europe convened a working group of medical professionals, hospital engineers and administrators, which discussed infectious and hazardous waste as a potential risk to public health in 1983.

The World Commission on Environment and Development (WCED) headed by Gro Harlen Bruntland proposed a set of legal principles for sustainable development and suggested a global convention for this purpose. For this purpose and for arresting further degradation of the environment and to repair damage already done, the Rio Earth Summit was convened by the UN General Assembly. Maintenance of ecological balance, prevention and control of environmental pollution, preservation of our natural resources, disaster mitigation and sustainable development are the basic factors of the "Earth Charter", which is also called the "Rio Declaration".

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65 UN GA Resolution 37/7. It was adopted by United Nations member nation-states on October 28, 1982.
67 A Norwegian politician, diplomat, and physician, and an international leader in sustainable development and public health. She is a former Prime Minister of Norway, and has served as the Director General of the World Health Organization.
68 World Commission on Environment and Development, Our Common Future, 1987
69 The United Nations Conference on Environment and Development (UNCED), also known as the Rio Summit, Rio Conference or Earth Summit was a major United Nations conference held in Rio de Janeiro from 3 June to 14 June 1992.
70 Rio Declaration on Environment and Development, 31 ILM 874, 1992
International treaties, Conventions, Conferences and Protocols resulted in regulatory legislation to protect the environment in several countries for framing policies to protect and improve environment, preventing pollution, punishing environmental crimes, and for compensating the persons affected by breach of protective provisions. Even before emergence of environmental laws, polluters were liable under the general principles of tortuous liability like nuisance.

There are, however, some international agreements and regulatory principles, which form the basis for healthcare waste management rules at the national level:

1. The **Basel Convention** signed by more than 100 countries concerns trans-boundary movements of hazardous waste. This Convention on the Control of Trans-boundary Movements of Hazardous Wastes and Their Disposal, usually known simply as the Basel Convention, is an international treaty that was designed to reduce the movements of hazardous waste between nations, and specifically to prevent transfer of hazardous waste from developed to less developed countries (LDCs). It does not, however, address the movement of radioactive waste. The Convention is also intended to minimize the amount and toxicity of wastes generated, to ensure their environmentally sound management as closely as possible to the source of generation, and to assist LDCs in environmentally sound management of the hazardous and other wastes they generate.
2. The **Polluter Pays Principle** implies that all producers of waste are legally and financially responsible for the safe and environmentally sound disposal of the waste they produce. In environmental law, the polluter pays principle is enacted to make the party responsible for producing pollution responsible for paying for the damage done to the natural environment. It is regarded as a regional custom because of the strong support it has received in most Organisations for Economic Co-operation and Development (OECD) and European Community (EC) countries. In international environmental law it is mentioned in Principle 16 of the Rio Declaration on Environment and Development.

3. The **Precautionary Principle** is a key principle governing health and safety protection. This principle states that if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is harmful, the burden of proof that it is not harmful, falls on those taking the action. This principle allows policy makers to make discretionary decisions in situations where there is the possibility of harm from taking a particular course or making a certain decision when extensive scientific knowledge on the matter is lacking. The principle implies that there is a social responsibility to protect the public from exposure to harm, when scientific investigation has found a plausible risk. These protections can be relaxed only if further scientific findings emerge that provide sound evidence that no harm will result.
4. The Duty of Care Principle stipulates that any person handling or managing hazardous substances or related equipment is ethically responsible for using the utmost care in the task. In English tort law, an individual may be owed a duty of care by another, to ensure that they do not suffer any unreasonable harm or loss. If such a duty is found to be breached, a legal liability is imposed upon the duty-owner, to compensate the victim for any losses they incur. The idea of individuals owing strangers a duty of care, where beforehand such duties were only found from contractual arrangements, developed at common law, throughout the 20th century.

5. The Proximity Principle recommends that treatment and disposal of hazardous waste takes place at the closest possible location to its source, thus aiming to achieve responsible self-sufficiency at a regional/or sub regional level. Where this is not possible, priority should be given to transportation by rail or water.

2.2 Legal Framework in United States of America

Viewing the USA law historically, it is seen that beginning on August 13, 1987 a “30-mile garbage slick” composed primarily of medical and household wastes prompted expansive closures of numerous New Jersey and New York beaches. Investigations ongoing throughout the year indicated that the waste likely originated from New York City’s marine transfer stations and the Southwest Brooklyn Incinerator and Transfer Station in particular. Then
the assistant commissioner of the New Jersey Department of Environmental Protection stated his belief that the cause of pollution was intentional rather than accidental since sealed plastic garbage bags were cut at the top, so their contents could disperse through the ocean. Such deliberate action is due to the high cost (~$1500/ton) associated with the legal disposal of the waste, whereby private waste contractors were tempted to dump wastes illegally in order to avoid high fees.

2.2.1 Medical Waste Tracking Act, 1988

It is reported that for the first time the Bio-Medical Waste Management issue was discussed at a meeting convened by the World Health Organisation (WHO) Regional Office for Europe at Bergen, Norway in the year 1983. The seriousness of the issue was brought to limelight during the “beach wash-ups” of summer 1988. Subsequent investigations carried out by the Environment Protection Agency (EPA) of USA in this regard culminated in the passing of the Medical Waste Tracking Act, 1988 (MWTA). With the passage of time the problem has evolved as a global humanitarian issue and there came into existence various types of regulatory laws in different parts of the world to manage and handle Bio-Medical Wastes in their own way. Therefore, any discussions on legal provisions of Bio-Medical Waste Management need to begin with the legal framework for this purpose in the

71 http://medind.nic.in/jab/t01/i4/jabt01i4p276.pdf visited on 3.7.2006
72 Sreejith A., Hygiene and Bio-Medical Waste Management plan for healthcare environmental setting: A study with special focus on Kerala, India. www.scribd.com visited on 5.7.2006
USA since they can be seen as pioneers in the field of legal control of Bio-Medical Waste Management by virtue of passage a legislation for this purpose.

The federal legislation has a “Medical Waste Tracking programme,”73 to which various states belong, unless indicted by the Governor of such a state by notifying the administrator. It also provides a list of Bio-Medical Wastes belonging to the programme, ranging from cultures and stocks of infectious agents and associated biological, pathological wastes, waste human blood and its products, sharps used on patients, contaminated parts of animals, wastes from surgery or autopsy that were in contact with infectious agents, laboratory waste, including commercial and industrial laboratories, dialysis wastes, discarded medical equipment and parts that were in contact with infectious agents, biological waste and discarded materials that are contaminated with secretions from those suffering from communicable diseases. It also includes a clause for other waste material resulting from medical care offered to a patient and as declared by the administrator. Hence the list is exhaustive.

Environment is ensured by providing for compliance orders that can be issued by the administrator, failing to comply with which, can bring upon the violator a fine of up to 25,000 dollars. There are also criminal penalties of

fine per day up to $ 50,000 and/or imprisonment of two years. However, for criminal penalty to apply, the person needs to have an intention to violate the tracking regulations, and hence, this being a difficult element to prove, it is rather superfluous. There is also a civil penalty, under which the violators are liable to pay upto $ 25,000 for each violation, from failures to segregate to dispose in a specific manner.

Designed primarily to monitor the treatment of medical wastes through their creation, transportation and destruction, i.e. from cradle-to-grave, the MWTA was approved to amend the Solid Waste Disposal Act to require the Administrator of the Environmental Protection Agency to promulgate regulations on the management of infectious waste. The MWTA was enacted, in short, as a pilot study to better determine how the life cycle of medical wastes played out under federal regulations.

Specifically, Medical Waste Tracking Act 1998 which amended the existing Solid Waste Disposal Act, 1976, did the following:

(i) It defined medical waste and established which medical wastes would be subject to program regulations.

(ii) It established a cradle-to-grave tracking system utilizing a generator initiated tracking form.

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74 (SWDA) This Act provides for comprehensive cradle-to-grave regulation of hazardous waste and authorizes environmental agencies to order the cleanup of contaminated sites. Since 1984, it has also called for the extensive regulation of underground storage tanks and the cleanup of contamination caused by leaking tanks.
(iii) It required management standards for segregation, packaging, labelling and marking, and storage of the medical waste.

(iv) It established record keeping requirements and penalties that could be imposed for mismanagement.

EPA promulgated the MWTA regulations on March 24, 1989. The regulations for this two year program went into effect on June 24, 1989 and expired on June 21, 1991 and were in effect in four states and Puerto Rico. During this time, EPA also gathered information and performed several studies related to medical waste management. The MWTA and EPA's associated program served to focus attention on the medical waste issue and provided a model for some states and other federal agencies in developing their own medical waste programs. After the repeal of the MWTA, States were given the responsibility to regulate and pass laws concerning the disposal of medical waste. Consequently all fifty states of the USA vary in their regulations for the disposal of Bio-Medical Wastes.

The MWTA also required EPA to examine various treatment technologies available at the time for their ability to reduce the disease causing potential of medical waste. The technologies that EPA examined in 1990 included:

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75 New York, New Jersey, Connecticut and Rhode island.
76 California, Florida, Georgia, Maine, Michigan, Missouri, Montana, Rhode Island, Vermont, Washington, West Virginia and Wisconsin are amongst the States that have prominent legislative regulations. The other States have either guidelines or policies only.
(i) incinerators and autoclaves (both onsite and offsite)

(ii) microwave units

(iii) various chemical and mechanical systems

Section 11002 of the MWTA, ‘Listing of Medical Wastes’, provides a listing of definitions on what materials will be classified as ‘medical wastes’ under the act. The list includes within its definitions: ‘cultures and stocks of infectious agents’, ‘pathological wastes’ such as body tissues, blood wastes and blood by-products, sharps, contaminated carcasses and beddings of animals, surgery or autopsy wastes that were once in contact with infectious agents, ‘laboratory wastes’, ‘dialysis wastes that were in contact with the blood of patients undergoing hemodialysis’, medical equipment having come in contact with infectious agents, and further contaminated biological materials. Defining what objects were to be classified as medical wastes was crucial to ensure that all municipalities under the MWTA would be monitoring similar materials.

Section 11003 dealt with ‘Tracking of Medical Waste’ and it outlined how the program should manage the transportation of waste materials. Four requirements were primarily identified. Firstly, to provide a means of monitoring ‘the transportation of waste from the generator to the disposal facility’ unless the said waste had previously been incinerated. Secondly to be able to ensure the ‘generator of the waste’ that the waste had been ‘received
by the disposal facility’. Thirdly, to develop a uniform system, for the tracking of materials across states and lastly, to develop a means to label and contain the wastes for the safety of the handlers.

Following this, Section 11004 on ‘Inspections’ provides provisions allowing for agents of the EPA to ‘enter … any establishment … where medical wastes are or have been generated’ so as to conduct ‘monitoring’, ‘testing’, or to ‘obtain samples from any person’. This process would allow for the EPA to legally enter generating facilities for the purpose of determining if infectious agents and materials were being handled as prescribed by the administrator of the EPA.

A major point of importance within the MWTA is its inclusion of specific enforcement provisions within the legislation. This becomes notable as it allows for one of the first instances in which an agency of the federal government may prosecute those charged with violation of regulations dealing with medical wastes. During the enactment of the MWTA the administrator of the EPA may be allowed to commence civil action in the United States district court in the district in which the violation occurred, against those being charged with the violation.

These regulations are also integrated with the state laws and hence even the state may conduct inspections, especially with regard to waste that
may be imported into a state, and the programme does not pre-empt any state or local laws except as to the form of tracking system. Hence, checks are laid at every stage to ensure compliance. Especially important is the ‘health impacts report’ that is drawn up every two years by the administrator of the agency for toxic substances and disease registry, which reports on the health effects of medical waste on the aspects like:

(i) the potential for infection or injury from the segregation, handling, storage, treatment or disposal of medical wastes;

(ii) an estimate of the number of people affected annually by sharps and the nature of the injuries;

(iii) an estimate of the public affected annually due to causes mentioned in (i) and (ii) and finally,

(iv) the diseases possibly spread by medical waste, like AIDS and an estimate of the number of cases traceable to medical waste.

In the USA, the cost of waste disposal has increased due to stiff environmental regulations, both at the state and federal level and the environmental standards are being further strengthened. Hence incinerators are to be used efficiently and according to set norms. Important in this regard is the Federal Clean Air Act, 1990 which sets out standards. In addition, there is a Code of Federal Regulations on Occupational Safety and Health Act, 1910, which deals in detail with the duty of employers to their employees in the hospital, dealing with their waste. This includes proper labelling,
segregation in relation to waste generation out of treatment given to persons with different types of diseases and hence segregation and regulation is at that very basic level. This includes even the description of the type of containers in which the waste is to be stored, the manner of cleaning them before reuse and also a description of dealing with the laundry.

2.3 Legal Framework in United Kingdom

The purpose of UK Waste Legislation is to control the keeping, transport and treatment, deposit and disposal of waste. It controls all sections of the waste management industry, including storage, registration, licensing, monitoring, record keeping and controls on specific Waste streams such as hazardous waste and clinical wastes.77

2.3.1 General Waste Management Legislative Framework

There are several laws in the UK generally applicable to waste regulation and they are:

The Birth Police (Scotland) Act, 1892 and 1903;

The Destructive Insects and Pests Act 1914;

The Persons Act, 1919;

The Public Health Act, 1936;

77 http://www.ciwn.co.uk/pma/1581 visited on 3.2.2006
The Drugs and Cosmetics Act, 1940;
The Industries (Development and Regulation) Act, 1951;
The Prevention of Food Adulteration Act, 1954;
The Solid Waste Disposal Act, 1955;
The Litter Act, 1958;
The Dangerous Litter Act, 1971;
The Deposit of Poisonous Waste Act, 1972;
The Water Act, 1973;
The Health and Safety at Work Act, 1974;
The Control of Pollution Act, 1974;
The Resource Conservation and Recovery Act, 1976;
The Insecticides Act, 1968 and

The whole system of waste management in hospitals is being done through segregation of the waste, keeping hazardous ones in red containers, less hazardous ones in yellow containers and the rest in black containers. However, studies revealed that a number of hospitals incinerated wastes at low temperatures leading to emissions rich in dioxin content.78

However, the waste legislation controlling the handling, collection and disposal of clinical waste is very extensive. The lack of understanding in the process of clinical disposal often results in unintentional breaking of laws.

78 Ibid.
Clinical waste regulations apply to any person or organisation that produces clinical waste. The ‘producer’ is responsible for care of their clinical waste while they hold it and for packing it appropriately to prevent its escape. The producer is also responsible for ensuring that all the regulations around clinical waste disposal are met. Moreover the description of the waste needs to be accurate and contain all the information necessary for safe handling, treatment and disposal.

2.3.2 Controlled Waste Regulations, 1992

In these rules, ‘clinical waste’ means (a) any waste which consists wholly or partly human or animal tissue, blood or other body fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, or syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and (b) any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it.79

2.3.3 The Environmental Protection Act, 1990

In this legislation, Section 34(1) of the Environmental Protection Act 1990 imposes a duty of care on any person who imports, produces, carries, keeps, treats or disposes of controlled waste or, as a broker, has control of such waste. The duty requires such persons to ensure that there is no unauthorised or harmful deposit, treatment or disposal of the waste, to prevent the escape of the waste from their control or that of any other person, and on the transfer of the waste to ensure that the transfer is only to an authorised person or to a person for authorised transport purposes and that a written description of the waste is also transferred.

The Duty of Care Regulations, 1991\textsuperscript{80} introduced under section 34(5) of the Environmental Protection Act, 1990 cast a duty on any person who is bound by the duty of care, to make and to retain documents and furnish copies of them to the concerned authorities. Breach of the duty of care or of these Regulations regarding documentation is a criminal offence. The duty of care and these Regulations do not apply to an Occupier of domestic property with respect to household waste produced on the property.

\textsuperscript{80} The Environmental (Duty of Care) Regulations, 1991.
One of the aims of the Duty of Care is to stop waste producers from simply handing over waste, without considering where it will be going. On a construction site, the waste producer is the person carrying out the work which gives rise to the waste, not the person who issues instructions or establishes contracts that give rise to waste. Where a haulier is brought by the main contractor to remove a sub-contractors waste, the main contractor is acting as a broker and all three parties are therefore subject to the duty.

Wherever waste is being stored, it must not be allowed to escape. This means that all containers/skips must be safe and secure, and they should also be labelled accurately. Waste should also be segregated to prevent mixing. It is the employer’s responsibility to make sure that all employees are aware of the location of the containers, and what can go in each.81

2.3.4 The Carriage of Dangerous Goods Regulations, 2007

According to these regulations, carrying goods by road or rail involves the risk of traffic accidents. If the goods carried are dangerous, there is also the risk of an incident, such as spillage of the goods, leading to hazards such as fire, explosion, chemical burn or environmental damage. Most goods are not considered sufficiently dangerous to require special precautions during

81 http://www.crwplatform.co.uk visited on 3.3.2006.
carriage. Some goods, however, have properties which mean they are potentially dangerous if carried.

Dangerous goods are liquid or solid substances and articles containing them, that have been tested and assessed against internationally agreed criteria by a process called classification and found to be potentially dangerous (hazardous) when carried. Dangerous goods are assigned to different Classes depending on their predominant hazard.

There are regulations to deal with the carriage of dangerous goods, the purpose of which is to protect everyone either directly involved (such as consignors or carriers), or who might become involved (such as members of the emergency services and public). Regulations place duties upon everyone involved in the carriage of dangerous goods, to ensure that they know what they have to do to minimise the risk of incidents and guarantee an effective response.

Carriage of dangerous goods by road or rail is regulated internationally by agreements and European Directives, with biennial updates of the Directives, taking account of technological advances. New safety requirements are implemented by Member States via domestic regulations which, for Great Britain, directly referring to the technical agreements.
2.3.5 The Hazardous Waste (England and Wales) Regulations, 2005

These regulations have certain key requirements as follows:

(a) The list of Hazardous Wastes is defined by the European Waste Catalogue under the List of Wastes Regulations, 2005.

(b) Each hazardous waste producing site, unless exempt, must be required to be pre-registered with the Environment Agency (EA) before waste can be collected.

(c) Consignees (hazardous waste receivers) must keep records of all consignments received and submit quarterly returns to the EA together with a fee per consignment.

(d) Sites that are registered will be subject to EA inspection and monitoring.

(e) The mixing of hazardous waste with other hazardous waste types and non hazardous waste is prohibited.

(f) All hazardous waste entering hazardous waste landfill sites and cells must also comply with the Waste Acceptance Criteria (WAC).

(g) Hazardous wastes will need to be sampled and tested in order to produce analysis results that can be used to determine whether a waste complies with WAC and can therefore continue to be landfilled.

The Regulations replaced the Special Waste Regulations and cover all wastes previously classed as ‘Special’. The full list is now defined by those
wastes marked with an asterisk in the European Waste Catalogue (EWC) which adds in over 200 different waste types.

The Regulations require that all hazardous waste producers are registered prior to any collections and it will be an offence for hazardous waste to be collected from a site that is not registered or exempt. The EA is encouraging registration through the internet by applying higher charges for paper based or telephonic registration and have developed a national database system that will provide a unique number for each site on registration. This number, along with specific consignment identification, must be on every consignment sent out from that site.

2.4 West Australian Waste Management Legal Framework

Western Australia occupies nearly one third of the Australian continent. Due to the size and the isolation of the state, considerable emphasis has been made of these features and no other regional administrative jurisdiction in the world occupies such a high percentage of a continental land mass. Hence this study has findings of the legal control of wastes in this part of Australia.

82 The rest of Australia does not have laws for Bio-Medical Waste Management, although policies and guidelines are followed.


2.4.1 Hospitals and Health Services Act, 1927

Certain terms are defined in statutes, for example, a public hospital under Section 2 of this Act means any hospital that is conducted or managed by a board constituted under this Act; or the Minister under this Act or declared to be a public hospital under Section 3 of the Act. Hospitals (Administration of Public Hospitals) Regulations 1940 made under this Act provide model bye laws for the guidance of boards of management of public hospitals in respect of the matters regarding which such boards may make bye laws.

2.4.2 Environmental Protection Act, 1986

It is important to note that an Environmental Protection Policy (EPP) made under this Act carries the greatest weight because EPPs have statutory force and regulations can be made to enforce them. Indeed the nomenclature of EPPs can lead to a misunderstanding of the legal effect of policies generally.

Administrative guidelines may be published by an agency of government to describe how one or more of the functions of that agency will be administered. An example of Administrative Guidelines are those published by the Environmental Protection Authority for the
process of environmental impact assessment under the Environmental Protection Act 1986; or the Administrative Guidelines published under the Environmental Protection and Biodiversity Conservation Act 1999 to aid the assessment procedure for referrals under that Act.

As far as Environmental regulation is concerned, it can reasonably be said that hospitals produce large quantities of waste. In metropolitan and country, sewerage and drainage areas, the Water Corporation, the Water and Rivers Commission and the relevant local government authority administer drainage and sewerage services.\(^{83}\)

The Environmental Protection Act 1986 and the regulations made pursuant to it contain the means to: prevent the generation of waste; recover the resources from waste; dispose of waste property; and manage the consequences of waste disposal.\(^{84}\)

Under the Environmental Protection Act, 1986, (EP Act) there is a tiered licensing system with three types of licences for emissions to air, land and water, which are regulated, monitored and best practice licences.\(^{85}\) Fees vary depending on the level of emission monitoring firms choose to follow. Firms or businesses who do not accurately monitor discharges hold

\(^{83}\) The Metropolitan Water, Sewerage and Drainage Areas are constituted by the Metropolitan Water Supply, Sewerage and Drainage Act, 1909 Sec 6. In areas outside the boundaries of the Metropolitan Water, Sewerage and Drainage Area, sewerage areas may be constituted, modified or dissolved.

\(^{84}\) Bates G M and Lipman Zada; Pollution Law in Australia 2002 Butterworths, at p. 236.

\(^{85}\) *Ibid.*
regulated licences; those who monitor discharges may hold monitored licences; and those who hold best practice licences have an approved environmental management system, an approved continuous improvement plan and conduct audits.\textsuperscript{86}

Under section 50(1) of the Environmental Protection Act 1986, a person commits an offence if he, she or it, intentionally or with criminal negligence (a) causes waste to be placed; or (b) allows waste to be placed, in any position from which the waste could reasonably be expected to gain access to any portion of the environment; and would in so gaining access be likely to result in pollution.

Furthermore, by section 51 of the EP Act, the Occupier of any premises commits an offence if it does not comply with any prescribed standard for the discharge of waste or the emission of noise, odour or electromagnetic radiation and takes all reasonable and practicable measures to prevent or minimize the discharge of waste and the emission of noise, odour or electromagnetic radiation, from those premises.

Under section 72 of the EP Act, if a discharge of waste, occurs as a result of an emergency, accident or malfunction occurs otherwise than in

\textsuperscript{86} \textit{Ibid.}
accordance with a works approval or licence or with a requirement contained in a pollution abatement notice; or is of a prescribed kind or a kind notified in writing to the Occupier concerned, and has caused or is likely to cause pollution, the Occupier of the premises on or from which that discharge took place who does not, as soon as practicable after that discharge, notify the Chief Executive Officer of the prescribed details of that discharge, commits an offence.

Under section 73 of the EP Act, if any waste has been or is being discharged from any premises otherwise than in accordance with a works approval or licence or a requirement contained in a pollution abatement notice, or a condition of pollution is likely to arise or has arisen, an inspector or authorized person may, with the approval of the Chief Executive Officer, give such directions in writing as the inspector or authorized person considers necessary to such person as he considers appropriate to remove, disperse, destroy, dispose of or otherwise deal with the waste which has been or is being discharged; or to prevent the condition of pollution from arising or control or abate that condition if it arises, as the case requires; or with such assistance as he considers appropriate to remove, disperse, destroy, dispose of or otherwise deal with the waste which has been or is being discharged; or prevent the condition of pollution from arising or control or abate that condition if it arises, as the case requires.
As far as the liability of Occupiers, the Occupier of premises must comply with any prescribed standard and must take all reasonable and practicable measures to prevent or minimise the discharge of waste from premises.\(^87\) The board of a hospital may be an Occupier which is liable for unlawful discharges of waste. Hospital waste may include general, industrial, hazardous and clinical waste\(^88\).

Perth public hospitals are not, prescribed premises under the Environmental Protection Act, 1986 and accordingly do require licensing under Part V of the EP Act, a licence must be obtained from the Department of Environmental Protection to discharge waste from prescribed premises;\(^89\) offensive trades described specifically under Schedule 2 of the Health Act, 1911; or noxious industries under the model scheme provisions to be found in Appendix B of the Town Planning Regulations, 1967 made pursuant to the Town Planning and Development Act, 1928. Accordingly, the works approvals or licences required under those Acts are not required for public hospitals.\(^90\)

There are a number of waste classifications and licence

\(^{87}\) See Regulation 5, and Schedule 1 of the Environmental Protection Regulations, 1987.

\(^{88}\) Hazardous waste is waste that is ignitable, corrosive, reactive, toxic or infectious. The DEP has not developed a Code of Practice for managing clinical waste but for the time being has adopted the national Code of Practice for the Management of Clinical and Related Wastes.

\(^{89}\) See Part V of the Environmental Protection Act, 1986.

\(^{90}\) However, various other activities undertaken at hospitals for example laundries, grease traps and oil traps will need licences from the Department of Environmental Protection.
requirements.\textsuperscript{91} Statutory requirements for licences or other environmental authorisations for the discharge, disposal and transport of waste; provisions for environmental management; and offences and penalties, generally depend on how waste is classified.\textsuperscript{92} Industrial waste is generally distinguished from other waste by definitions in the regulatory framework that governs their disposal.

Prior to its commencement a hospital that seeks to discharge its industrial waste into the sewerage system must obtain approval from the Water Corporation.\textsuperscript{93} In making the application the hospital must give details of all the types of effluents and pre-treatment works, and may be required to install special monitoring equipment. The approval will be in the form of an industrial waste permit.\textsuperscript{94} In addition hospitals attract quality and quantity (QQ)\textsuperscript{95} charges, to reflect the load which they add to the system and to determine the cost of the service provided by the Water Corporation.

Under the Metropolitan Water Supply, Sewerage and Drainage Byelaws, 1981, whether or not a particular hospital is complying with its obligations is unlikely to be discovered unless a major polluting event

\textsuperscript{91} See Halsbury’s Laws of Australia.
\textsuperscript{92} Ibid
\textsuperscript{93} For example at the Sir Charles Gardiner hospital area there are several such permits each relating to each entity that resides in the hospital vicinity.
\textsuperscript{95} Ibid
discovered at the treatment plant can be tracked back to the offending hospital. The Water Corporation is the sole judge of the quality, quantity and rate of industrial waste discharge and whether a discharge complies with a permit issued by it.\textsuperscript{96} Accordingly, as long as a public hospital pays the annual licence fee and complies with any conditions attached to the permit it will be left alone.\textsuperscript{97}

If the Water Corporation suspects a breach of an industrial waste permit, it may issue a notice to the Occupier to make good the damage; may terminate the permit; or recover costs from the Occupier for remediation works done. It is an offence not to comply with a notice.\textsuperscript{98}

**2.4.3 Health Act, 1911**

It is an offence under this Act for a person to allow or cause chemical refuse, waste or any liquid over a temperature of 43 degrees into a sewer of, or any drain communicating with a sewer of a local government where that matter causes a nuisance, is injurious to health or

\textsuperscript{96} See the Metropolitan Water Supply, Sewerage and Drainage Bye-laws 1981 as amended.

\textsuperscript{97} Where there is a release of certain contaminants pre-treatment fixtures may be required to be or ought to be put into place such as grease arresters, petrol/oil arresters, sand arresters, neutralisers and dilution pits.

\textsuperscript{98} *Ibid.*
interferes with the disposal of sewage.

2.4.4 Metropolitan Water Authority Act, 1982

It is an offence under this Act to cause or permit sediment or other pollutant to enter a main drain in the Metropolitan Water, Sewerage and Drainage Area.\(^{100}\) The Water Corporation may give a notice to any person or corporation who commits an offence to repair any damage and remove any cause of pollution. Failure to comply with the notice is an offence.\(^{101}\)

2.5 European Legal Framework

Depending on whether or not they are EU countries, the approach varies. EU countries have a specific legislative framework. The European Waste Catalogue (EWC) applies and there are Incineration Directives, Landfill Directives and National Waste Regulations for such countries.

2.5.1 Directives for EU Countries

Wastes are defined by their European Waste Catalogue (EWC) Codes. EWC Codes are 6 digits long, with the first two digits defining the over-

\(^{99}\) See the Health Act, 1911 Sec. 94, and see Farlodge v Rough (unreported decision of the Supreme Court of Western Australia) Murray J No 1131 of 1992, 12 January 1993, for the vicarious liability of an employer for breach of section 94 by its employees.

\(^{100}\) See the Metropolitan Water Authority Act, 1982 Secs. 101(1)(b) & 101 (1)(c).

\(^{101}\) See the Metropolitan Water Supply, Sewerage and Drainage Bye-laws 1981 bye-law 4.9.
arching category of waste, the next two defining the sub-category and the last two defining the precise Waste stream. Clinical waste comes under the “18” codes, for example: “18 01 01” corresponds to healthcare waste (18), from humans (01), that is sharp and not infectious (01).\textsuperscript{102}

The Landfill Directive, more formally Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, is a European Union Directive issued by the European Union to be implemented by its member states. The Directive’s overall aim is to prevent or reduce as far as possible negative effects on the environment, in particular the pollution of surface water, groundwater, soil and air, and on the global environment, including the greenhouse effect, as well as any resulting risk to human health, from the land-filling of waste, during the whole life-cycle of the landfill. This legislation also has important implications for waste handling and waste disposal.

\textbf{2.5.2 Policy of Non-EU Countries}

Non EU countries have either no legislative framework or it is not implemented. However, WHO waste management policies and Persistent Organic Pollutants (POPs) treaty are applicable. The guiding principles of WHO activities include preventing the health risks associated with exposure to health-care waste for both health workers and the public by promoting

\textsuperscript{102} http://en.wikipedia.org/wiki/Medical-waste visited on 5.2.2006
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; and reducing the exposure to toxic pollutants associated with the combustion process through the promotion of appropriate practices for high temperature incineration.

The strategy is to better understand the problem of health-care waste management, WHO recommends that countries conduct assessments prior to making any decision as to which health-care waste 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 different strategies.

Short-term strategies include 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, etc.); and research and promotion on new technologies or alternatives to small-scale incineration.

Until countries in transition and developing countries have access to healthcare 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 strategies include further efforts to reduce the number of unnecessary injections thereby reducing the amount of hazardous health-care waste that needs to be treated; research into the health effect of chronic exposure to low levels of dioxins and furans; and risk assessment to compare the health risks associated with: (1) incineration; and (2) exposure to health-care waste.

Long-term strategies include 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.

2.5.3 Medical Waste Management in Croatia

Special mention needs to be made of Croatia, which is a non EU member but has a well regulated waste management legal regime. Medical waste management here is regulated by three fundamental legal Acts: Waste Act 2004, Ordinance on Waste Types and Directive on manipulation of waste generated in Healthcare. The implementation of these Acts and waste management in general are also supported by the legislation dealing with Transport of Hazardous materials and that of Toxic Substances. Modern trends in waste management promote an integrated approach also called ‘waste chain’. This integrated approach to medical waste management is based on hierarchical structuring of waste management structure from the point where it is produced to its final disposal. Priority is always accorded to reducing the amount and the harmfulness of waste by replacing harmful materials with those that are not, but where it is not possible, waste management includes sorting and separating, pre-treatment on site, safe transportation, final treatment and sanitary disposal. Methods of choice for final treatment should not be harmful for human health and environment. Even though Croatian regulations define and cover all steps in the waste

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103 Officially, the Republic of Croatia is classified as an emerging and developing economy by the International Monetary Fund and a high income economy by the World Bank.
management chain, their implementation is one of the country’s greatest issues. Improper practices are seen, right from waste production in healthcare institutions to the final disposal and include handling, sorting, and use of containers or treatment in incinerators. In addition, Croatia lacks locations for sanitary landfills.\footnote{http://www.researchgate.net/publication/6677053_Medical_waste visited on 7.2.2006}

2.6 Legal Framework for Waste Management in South Africa

In South Africa, the researcher has identified effective regulations in Gauteng - the smallest province in the Republic with only 1.4% of the land area, but highly urbanised, containing the cities of Johannesburg and Pretoria.

2.6.1 Healthcare Waste Management Regulations, 2003

The province of Gauteng has these regulations, which apply to all persons who generate, collect, receive, store, transport, treat, dispose of, or handle healthcare risk waste in any form in the Province of Gauteng. It defines ‘healthcare waste generator’ means any person, whose acts or processes produce healthcare waste and includes, but is not limited to:

(a) Home based care givers and organisations;
(b) Medical and Dental Practitioners, clinics, hospitals, surgery centres, laboratories, research laboratories, and General Practitioners;
(c) Veterinary Practitioners, Clinics, and Hospitals;

(d) Traditional Healers; and

(e) Tattoo Artists; Body Pierces, Undertakers, and Embalmers.

It lays down a general prohibition and duty of care, focuses on segregation, waste minimization, packaging, internal transport, treatment and disposal of healthcare waste. Other issues of concern in these regulations are authorization to generators of healthcare waste, reporting, record keeping and audit reports.\textsuperscript{105}

For the purpose of enforcement, healthcare risk waste inspectors are appointed who have certain powers of inspection and causing the production of documents and a Chapter is devoted to the offences and penalties and there are punishments and fines provided along with award of damages and other civil remedies. The regulations include several Schedules with Standards for treatments of different types.\textsuperscript{106}

\section*{2.7 Waste Management Legal Framework in Asia}

The researcher has identified the hospital waste management practices in a few Asian countries, viz. Japan, People’s Republic of China and several of the South Asian countries, since they are neighbours to the Indian sub-

\textsuperscript{105} These provisions are similar to the Indian legal provisions discussed at pp. 103-132
\textsuperscript{106} http://www.elaw.org/node/2852 visited on 4.5.2006
continent. As for the south Asian countries, a comparative analysis has been drawn and the Indian legal scene has been included in the comparison.

2.7.1 Waste Disposal Law of 1970 in Japan\(^{107}\)

In Japan, the waste management practice is carried out in accordance with this ‘law’. The first rule of infectious waste management was regulated in 1992 and infectious wastes are defined as the waste materials generated in medical institutions as a result of medical care or research which contain pathogens that have the potential to transmit infectious diseases. Revised criteria for infectious waste management were promulgated by the Ministry of Environment in the year 2004. Infectious waste materials are divided into three categories: the form of waste; the place of animal generation; the kind of infectious diseases.\(^{108}\)

This Japanese waste management law which was enacted in 1970 and last amended in the year 2000, provides for the definition and classification of wastes; standards for waste treatment; establishing national policy and regional/municipal programme on waste management; treatment of municipal wastes by municipalities; authorization for waste transporters, treatment

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\(^{107}\) Japanese legal system does not use the term ‘Act’ for a legislation, but terms it as ‘Law’

facilities and landfills; manifest system for industrial waste and about official inspections and penalties.\textsuperscript{109}

### 2.7.2 Law of People’s Republic of China on Environmental Protection, 1989

In The Peoples Republic of China, sustainable management of healthcare wastes (HCW) takes into account the requirements deriving from the Stockholm Convention on Persistent Organic Pollutants (POPs) and the WHO recommendations. Although there were two laws on the subject, this is the principal law on Environmental Protection in China. The other law is a special law for prevention, control and elimination of infectious disease and protection of human health, viz. Law of the People’s Republic of China on Infectious Disease Control and Prevention, 1989; and although there have been various standards laid down in the year 2001,\textsuperscript{110} it was only after a few years that special administrative regulation for Chinese healthcare waste management was introduced called the Healthcare Waste Management Regulation, 2003. One important basis of this management process, stimulated five categories of Healthcare Waste as infectious waste, pathological waste, sharp objects, chemical waste and pharmaceutical waste and this was recognized through another regulation called Medical Waste Category 2003 which was soon thereafter followed by stipulated


\textsuperscript{110} Incineration Pollution Control standard, Storage Pollution Control standard and Landfill Pollution Control Standard.

By the end of 2005, there were 149 low-standard Healthcare Waste disposal facilities in operation in China, distributed throughout different areas. According to the National Hazardous Waste and Healthcare Waste Disposal Facility Construction Plan, 331, modern, high-standard, centralized facilities will be built up in China in municipal level cities. Although incineration is still the main technical option for HCW disposal in China, it is expected that, especially for medium and small size facilities, non-incineration technologies will develop quickly and will soon become the main technical option. The basic management needs, both from the point of view of pollution control and final disposal, have been defined, and a system of technical and environmental standards has been formulated and implemented. However, there are still some shortages. This is particularly true when considering the best available techniques and best environmental practices developed under the Stockholm Convention, with which the present technological and managing situations are not completely compliant. In this framework, the lifecycle (from generation to final disposal of wastes) of HCW and holistic approaches (technology verification, facilities operation, environmental supervision, environmental monitoring, training system,
financial mechanism, etc.) towards HCW management are the most important criteria for the sustainable and reliable management of HCW in China.

2.8 Bio-Medical Waste Management Legal Framework in South Asian Countries

As far as the South Asian countries are concerned, the researcher identified the legal control of Bio-Medical Wastes in certain countries. The legislative measures, in Bangladesh, Bhutan, Maldives, Nepal, Pakistan and Sri Lanka were examined in this study.

It is seen that apart from India, which has a specific set of Rules from the year 1998 and Pakistan, which has Rules for hospital waste management from the year 2005, other South Asian countries do not have any specific legal control over the management and handling of Bio-Medical Wastes, even though there are legislative measures for the protection of the environment.

Table 2.1 provides a comparative analysis of the state of healthcare waste legislations and policies in the mentioned countries of the South Asian region vis-à-vis India.
### Table 2.1

<table>
<thead>
<tr>
<th>Country</th>
<th>Legal Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>No specific rules covered in the Environmental Protection Act, 1995 of the country.</td>
</tr>
<tr>
<td>Maldives</td>
<td>No separate rules in Environmental Protection and Preservation Act, 1993 of the country.</td>
</tr>
<tr>
<td>Nepal</td>
<td>No polices and legislation dealing with hazardous wastes.</td>
</tr>
<tr>
<td>Pakistan</td>
<td>Hospital Waste Management Rules, August 2005.</td>
</tr>
</tbody>
</table>

### 2.9 Conclusion

The international legal mechanisms for the control of general wastes are of different character in different parts of the world. This study has revealed that Bio-Medical Waste Management was earlier controlled through laws governing general waste management in almost all countries, till such time specific law was enacted for this purpose. The legal framework in the USA is the starting point in the enactment of specific law for this purpose,
following which several countries of the world took initiatives in this direction.

Even before the environmental law took shape, the regulatory principles which formed the basis of healthcare management existed. Apart from this, the International treaties, Conventions and protocols also resulted in regulatory legislation to protect the environment in some countries, which included preventing pollution and enacting legislation for the control of waste management. Therefore, every country has some law to protect the environment and control waste management and this study has highlighted the legal framework in the United Kingdom, Western Australia, Europe, South Africa, Asian and South Asian countries. Apart from the USA, a few amongst these countries have specific laws to manage Bio-Medical Wastes, notable amongst them being the Guateng Province in South Africa and India being the first amongst the South Asian countries to have a specific legal control for this purpose.