

BASEL CONVENTION

FINAL DRAFT

**TECHNICAL GUIDELINE ON THE ENVIRONMENTALLY
SOUND MANAGEMENT OF BIOMEDICAL AND
HEALTHCARE WASTE (Y1; Y3)**

Foreword

A series of national guidelines from developed and developing countries, in particular a comprehensive WHO Publication, which covers a very wide spectrum, and a CEN paper formed the basis for this Guideline.

Concerning the definition and classification of biomedical and healthcare waste these papers include two fundamental different concepts, especially for infectious waste. One proposal among others made by the WHO prefers a wide definition and classification of infectious waste which in principle covers all waste contaminated with blood and other body fluids and thus to exclude all - even theoretical - pathways for infectious diseases (precautionary principle). For the following laid down and described routes for the disposal of the waste, more pragmatic and cost-effective solutions (e.g. disposal together with household waste) are suggested, meaning however that the desired high safety aspects can not be ensured for the whole disposal process.

This guideline does not follow the approach of a wide definition.

This guideline follows an approach to reduce hazardous and problematic waste streams to a minimum by means of

- High qualification of staff
- Strict definition and classification of the waste stream and
- Segregation at the source of the waste with the best information for identification of the waste.

Only for this reduced amount of waste, but still covering the main sources of the hazardous waste, are specialised waste disposal techniques needed. This will lead to a well organised disposal of biomedical and healthcare waste with justifiable costs.

Because of the different levels of waste management infrastructure, capacity and capability among Parties solutions are required that are suitable and feasible. In that spirit, the technical guidelines describe how to move towards state-of-the-art management of biomedical and healthcare wastes, while at the same time identifying other kinds of suitable possibilities.

The major points of this Guideline are the practical aspects of waste management pertaining to the handling and environmentally sound management of biomedical and healthcare wastes. Other aspects were only dealt with as seemed necessary.

These technical guideline should be considered in conjunction with other technical guidelines adopted by the Conference of the Parties to the Basel Convention and governing the environmentally sound recovery and disposal of wastes, in particular, the Technical Guidelines for Incineration on Land (D 10) and on Specially Engineered Landfill (D 5). In addition, special regard should be given to the legal frameworks and the responsibilities of the relevant competent authorities.

Because of the fact that radioactive wastes which are not covered by the Basel Convention are found, for example, in the medical sector, it was necessary that some fundamental instructions be made regarding the handling of such wastes. Many of the radio nuclides used in nuclear medicine and biological research have short half-lives and therefore radioactive decay causes the radioactive hazard of the waste to fall below clearance levels in a relatively short period of time. At this stage, the waste would be subject to the Basel Convention.

The management of radioactive waste is subject to national or international regulations, i.e. the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Comprehensive guidance on all aspects of the safety of radioactive waste management is provided in the Safety Standards Series of the International Atomic Energy Agency. Reference is made in chapter 4.7 to several IAEA publications which are relevant in the context of this guideline.

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1 Introduction

1. The disposal of wastes originating from (public and private) healthcare establishments can have an effect on:

- the health and human well-being,
- the environment (air, water, soil, animals, plants, landscape)
- issues relating to the public security and order.

2. Nevertheless, experience has proven that wastes originating from health-care establishments, when properly managed, generally pose no greater risks than that of properly treated municipal or industrial wastes. This also pertains to the disposal of biomedical and healthcare wastes, in contrast to occasional public perception.

3. The guideline provides information for the proper treatment of wastes from (public and private) healthcare establishments. The provided information takes due consideration of the waste management requirements of disposal and recovery measures as well as the requirements of hygiene. In addition to ecological aspects, the information and recommendations should be economically feasible, easy to undertake and also make allowances for technical progress.

4. It has become apparent that introduction of improved solutions for the segregation of waste within healthcare facilities can result in reduced amounts of waste requiring special treatment and therefore in reduced waste treatment costs. In addition, new technologies have become available to treat and disinfect biomedical and healthcare wastes so that they finally can be disposed with low risk by landfilling.

5. In many countries, landfill has been and continues to be the predominant method for direct disposal of wastes - most frequently without pre-treatment. There is considerable concern about this practice.

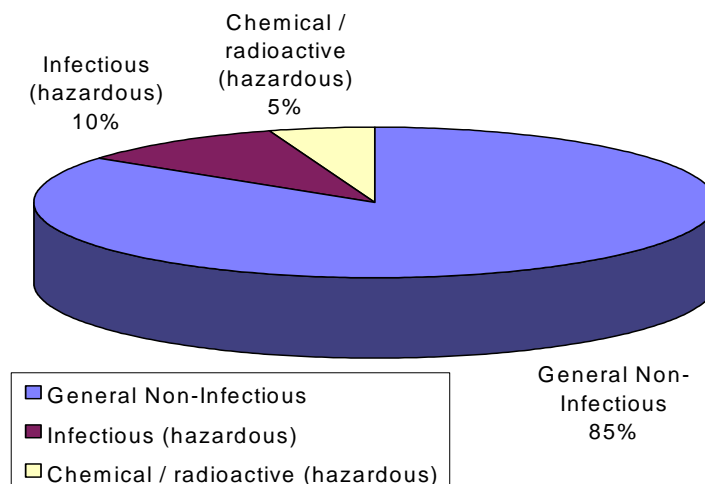
6. The safe management of biomedical and healthcare waste is essential for community and environmental health. It is also important that, irrespective of technologies used for treatment and disposal, the standards for the protection of the environment and human health are uniform across all the healthcare establishments. This in turn ensures a more viable and efficient industry. However, it should be noted that in many countries, the national authorities, in addition to industry, is an active participant in healthcare, either providing services or paying for them. Additionally, the lack of resources or of experience in developing standards may be significant factors affecting the capacity to treat biomedical and healthcare wastes.

7. To manage biomedical and healthcare waste effectively, consideration needs to be given to:

- generation and minimisation;
- source separation and segregation;
- identification and classification;
- handling and storage;
- packaging and labelling
- transportation inside and outside of healthcare establishments;
- treatment;
- disposal of residues (including emissions);
- occupational health and safety; public and environmental health;
- stakeholder and community awareness and education;
- research and development into improved technologies and environmentally friendly practices.

8. This guideline attempts to address all of these issues and provide support for the achievement of improved environmental performance in managing biomedical and healthcare waste. To be successful, waste management strategies must often take account of, and interact with, the process that generated the wastes in the first place.

Picture 1: Waste from clinics and hospitals
(source: The American Hospitals Association)



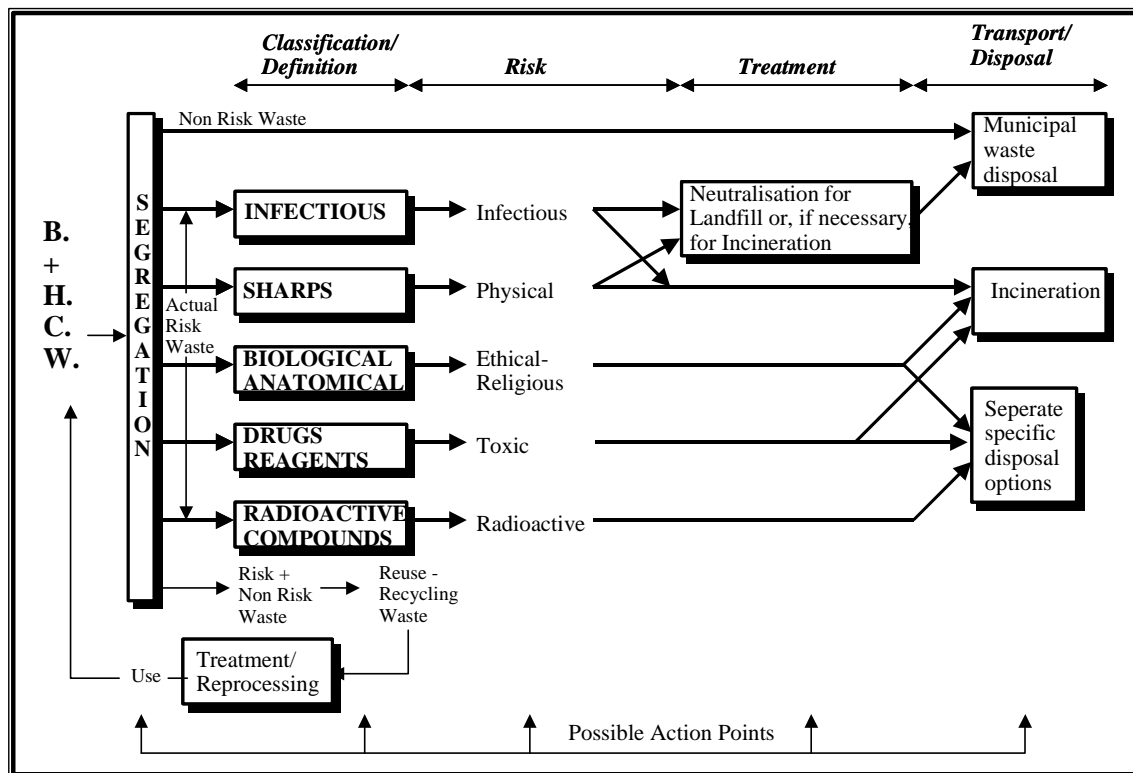
9. Based on observations at several healthcare establishments in the world the average biomedical and healthcare waste stream contains less than 10% of

materials that could be considered "potentially infectious", if properly segregated the content of infectious waste can be reduced to 1 –5 % of the waste arising in healthcare establishments.

2 Purpose and scope of the guideline

10. Biomedical and healthcare waste are terms used for all waste arising from healthcare establishments. Biomedical and healthcare waste can briefly be described as waste from medical or other related practices. In reality only a small proportion of this waste cause a higher risk of transmitting infectious diseases than normal household or municipal waste. This guideline deals with all biomedical and healthcare waste, but focuses on segregation and treatment of hazardous biomedical and healthcare waste.

Picture 2: Biomedical and Healthcare Waste Strategy



11. Concern over the safe management and disposal of biomedical and healthcare waste has resulted from the perceived or real risk of potential transmission of infectious diseases through accidental injury or contact with infected body fluids. The disposal of sharps (needles, scalpels etc.) has attracted particular interest because the small number of occupationally acquired hepatitis and HIV infections suffered by healthcare workers attributed to the result of sharps injuries. The majority of sharps injuries, however, do not result in infection.

Therefore it is "good practice" in waste management to reduce the risk of injuries. Picture 2 describes some possible action points to establish "good practice" in waste management.

3 General Definition of biomedical and health-care waste

12. To get a better understanding of the waste management practice of healthcare facilities there is a need to have a common and internationally accepted definition for the waste generated in those facilities.

13. The following general definitions are set by this guideline:

Healthcare:

Medical activities such as diagnosis, monitoring, treatment, prevention of disease or alleviation of handicap in humans or animals, including related research, performed under the supervision of a medical practitioner or veterinary surgeon or another person authorised by virtue of their professional qualifications.

Biomedical and Healthcare Waste:

The solid or liquid waste arising from healthcare (including collected gaseous waste).

Hazardous Healthcare Waste:

- Infectious healthcare waste
- Chemical, toxic or pharmaceutical waste including cytotoxic drugs (antineoplastics)
- Sharps (e.g. needles, scalpels)
- Radioactive waste
- Other hazardous waste^{♦)}

Infectious Healthcare Waste:

All biomedical and healthcare waste known or clinically assessed by a medical practitioner or veterinary/surgeon to have the potential of transmitting infectious agents to humans or animals.

^{♦)} For further information the WHO-Guideline "Safe Management of Wastes from Healthcare Activities" is recommended. See also para 33.

The interpretation of the definition of infectious healthcare waste varies according to national circumstances, policies and regulations; other international organizations have specific interpretations of the definition (such as WHO^{*}), International Transport Regulation). Infectiousness is one of the hazard characteristics contained in Annex III to the Basel Convention and defined in H6.2[^]).

For the purpose of these guidelines, infectious healthcare wastes are:

- a) discarded materials or equipment contaminated with blood and its derivatives, other body fluids or excreta from infected patients with hazardous communicable diseases (specified in Chapter 6.1, No. 38). Contaminated waste from patients known to have blood borne infections undergoing haemodialysis (e.g. dialysis equipment such as tubing and filters; disposable sheets, linen, aprons, gloves or laboratory coats contaminated with blood).
- b) Laboratory waste (cultures and stocks with any viable biological agents artificially cultivated to significantly elevated numbers incl. dishes and devices used to transfer, inoculate and mix cultures of infectious agents and infected animals from laboratories).

Wherever appropriate and applicable, waste from basic and fundamental biomedical and other research shall be managed according to the principles set out for healthcare waste.

Biological Healthcare Waste:

All body parts and other anatomical waste including blood and biological fluids and pathological waste that are recognisable by the public or the healthcare staff and that demand, for ethical reasons, special disposal requirements.

Sharps:

All biomedical and healthcare waste with sharps or pointed parts able to cause an injury or an invasion of the skin barrier in the human body. Sharps from infected patients with hazardous communicable diseases (specified in Chapter 6.1, No. 38), isolated wards, or other pointed parts contaminated with above mentioned laboratory waste must be categorised as infectious waste.

^{*}) Compare WHO-Guideline "Safe Management of Wastes from Health-care Activities"

[^] Further elaboration of the characteristics is the subject of working papers under discussion by the Technical Working Group.

4 Hazards of biomedical and healthcare waste

4.1 Types of hazards

14. As mentioned in chapter 1, biomedical and healthcare waste includes a large component of non-risk waste and a smaller proportion of risk waste. Non-risk waste is similar to municipal waste and does not create more health or other hazards than mismanaged municipal waste. If the risk waste is not properly segregated from other waste fractions (e.g. mixture of biological and pathological waste with sharps and body fluids) the whole mixture has to be handled as infectious waste. In this chapter potential hazards related to exposure to biomedical and healthcare waste will be addressed.

15. Exposure to hazardous or potentially hazardous biomedical and healthcare waste can induce disease or injury. The hazardous nature of biomedical and healthcare waste may be due to the following or a mixture of the following properties:

- it contains infectious agents, incl. contaminated sharps;
- it is cyto- or genotoxic;
- it contains toxic or hazardous chemicals or pharmaceuticals;
- it is radioactive;
- it contains sharps.

16. For the purposes of this guideline infectious substances are those substances known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant micro-organisms (hybrid or mutant), that are known or reasonably expected to cause infectious disease with a high risk for animals or humans. Notice that not all pathogen micro-organisms can be transmitted by waste as pathway.

4.2 Persons at risk

17. All persons exposed to hazardous biomedical and healthcare waste are potentially at risk of contamination through accidental exposure. This includes people within healthcare establishments or any other source of biomedical and healthcare waste, and people in- and outside these sources who either handle these wastes or are exposed to it e.g. as a consequence of careless management. The main groups at risk are the following:

- Doctors, nurses, ambulance staff and hospital sweepers;
- Patients in healthcare establishments or under home care;
- Workers in support services to healthcare establishments, such as laundries, waste handling and transportation, and waste disposal facilities including incinerators; other persons separating and recovering materials from waste.
- Inappropriate and/or inadvertent end users such as scavengers and customers in Secondary markets for re-use (i.e. households, local medical clinics, etc.)

18. Due to the extension of drug abuse, and of home care including home dialysis, the hazards associated to scattered small sources of biomedical and healthcare waste should not be overlooked.

4.3 Hazards from infectious waste

19. Infectious waste may contain a great variety of pathogenic micro-organisms, but not all can be transmitted to humans and animals by contact with waste.

20. These pathogens contained in the waste may infect the human body through the following pathways:

- absorption through a crack or cut in the skin (injection);
- absorption through the mucous membranes; and rarely by
- inhalation and
- ingestion.

21. Concentrated cultures of pathogens and contaminated sharps (in particular syringe needles) are probably the waste items creating the most acute human health hazards.

Table 1: Classification of risks; suggested remedies

| Risk attached to → | ACTUAL RISKS | | | | | | | | PERCEIVED RISKS | |
|------------------------------------|-------------------|-----------|-----------------------|-----------|-----------------|-----------|--------------------------------|-----------|-------------------------------|-----------|
| | INFECTION | | | | | | TOXIC | | EMOTIONAL | |
| | Pricking, cutting | | Inhalation, ingestion | | Existing wounds | | Contact, ingestion, inhalation | | Sensibility, ethical position | |
| | scale | reduce by | scale | reduce by | scale | reduce by | scale | reduce by | scale | reduce by |
| A. Within healthcare areas | | | | | | | | | | |
| Category of person | | | | | | | | | | |
| Patient | - | I | ± | P,I | + | P,I | + | P,I | + | I |
| Healthcare personnel | + | P,I | + | P,I | + | P,I | + | P,I | ± | I |
| Logistic personnel | + | P,I | + | P,I | + | P,I | + | P,I | + | I |
| Other personnel | 0 | | - | P,I | 0 | | 0 | | + | I |
| Visitors and service contractors | 0 | | - | I | 0 | | 0 | | + | I |
| B. Outside healthcare areas | | | | | | | | | | |
| Category of person | | | | | | | | | | |
| Transport personnel | + | P,I | ± | P,I | ± | P,I | + | P,I | + | I |
| Treatment personnel | + | P,I | ± | P,I | ± | P,I | + | P,I | + | I |
| Members of the public | 0 | | 0 | | 0 | | 0 | | + | I |

Key to column symbols:

(a) scale of risk:

0 is trivial risk; - is low risk; ± is average risk; + is high risk

(b) means of reducing risk:

P is by Prevention, i.e. good practice (segregation ...), indirect means (sterilisation of waste), and training (on hygiene and safety).

I is by Information (communicating hygiene rules, public information, effective training).

4.4 Hazards from sharps

22. Sharps may not only cause cuts and punctures, but also infect the wounds by agents which previously contaminated the sharps. Due to this double risk of injury and disease transmission, sharps are considered as problematic. The main diseases of concern are infections which may be transmitted by subcutaneous introduction of the agent, e.g. viral blood infections.

23. Syringe needles are of particular concern because they constitute an important part of the sharps and are often contaminated with patients blood.

4.5 Hazards from chemical and pharmaceutical waste

24. Many chemicals and pharmaceuticals which are used in healthcare establishments are hazardous chemicals (e.g. toxic, corrosive, flammable, reactive, explosive, shock sensitive, cyto- or genotoxic). Fractions of these will be found in biomedical and healthcare waste after their use or when they are no longer required.

25. They may cause toxic effects, either by acute or by chronic exposure, and injuries, including burns. Intoxications can result from absorption of the chemicals/pharmaceuticals through the skin, the mucous membranes, from inhalation or ingestion. Injuries can be provoked by contact of flammable, corrosive or reactive chemicals with the skin, the eyes or the mucous membrane of the lung (e.g. formaldehyde and other volatile chemicals). The most common injuries are burns.

26. Mercury constitutes another hazardous issue within hospitals due to its prevalent use literally hundreds of different devices most concentrated in diagnostic devices such as thermometers, blood pressure meters, esophageal dilators, Miller Abbott/Cantor tubes. It is also found in more mercury sources such as fluorescent light tubes and batteries.

27. Disinfectants constitute a particularly important group, as they are used in large quantities and are often corrosive. It should also be noted that reactive chemicals may form secondary compounds of high toxicity.

28. Chemical residues discharged into the sewage system may have toxic effects on the operation of biological sewage treatment plants or on the natural ecosystems of receiving waters. Pharmaceutical residues may have the same effects, as they may include antibiotics and other drugs, heavy metals such as mercury, phenols and derivatives and other disinfectants and antiseptics.

4.6 Hazards from cytotoxic waste

29. The severity of health hazards for healthcare workers handling cytotoxic waste is the combined effect of the substance toxicity and of the magnitude of exposure, which may occur during waste handling or disposal. Exposure to cytotoxic substances in healthcare may also occur during preparation for treatment. The main pathways of exposure are inhalation of dust or aerosols, skin absorption, and ingestion of food accidentally in contact with cytotoxic (antineoplastic) drugs, chemicals or waste, or from contact with chemotherapy patients secretions.

4.7 Hazards from radioactive waste

30. Radioactive materials are unique in causing harm through both external radiation (by approaching them or handling them) and also as a result of their intake into the body. The degree of harm depends upon the amount of radioactive material present or taken into the body and on the type of the radioactive material. Exposure to radiation from high activity sources, such as those used in radiotherapy, can cause severe injuries, ranging from superficial burns to early fatalities. Radioactive waste arising from nuclear medicine is much lower in activity than the sources referred to above and is unlikely to cause such harm, but exposure to all levels of radiation is considered to be associated with some, however small, risk of carcinogenesis.

31. There are well established procedures for minimising the hazards in work with radioactive materials and these are normally implemented in hospitals and laboratories where such materials are used. Similarly, the arrangements for safe radioactive waste storage and disposal are well established. There should be a person or persons appointed in the organisation with responsibilities for ensuring that radiation protection are observed and radioactive waste is properly and safely managed. International recommendations^{*)} on the safe management of radioactive wastes are established by the International Atomic Energy Agency (IAEA) and are applicable to their control in healthcare.

*) Management of radioactive wastes produced by users of radioactive materials, Safety Series No. 70, IAEA, Vienna (1985).

Handling, treatment, conditioning and storage of biological radioactive wastes, IAEA-TECDOC-775 (1994).

Management of small quantities of radioactive waste, IAEA-TECDOC-1041 (1998)

5 Field of application/source identification

32. The guideline shall be applicable for biomedical and healthcare wastes generation from healthcare establishments. Healthcare establishments shall specifically include the following:

LARGE SOURCE

- University hospitals and clinics
- Maternity hospitals and clinics
- General hospitals

MEDIUM SOURCE

- Medical centres
- Out-patient clinics
- Mortuary/autopsy facilities
- Farm and equine centres
- Hospices
- Abortion clinics
- Medical laboratories
- Medical research facilities
- Animal hospitals
- Blood banks and transfusion centres
- Emergency services

SMALL SOURCE

- General medical practitioners
- Convalescent homes
- Nursing and remedial homes
- Medical consulting rooms
- Dental Practitioners
- Animal boarding and hunt kennels
- Tattooists
- Acupuncturists
- Veterinary Practitioners
- Pharmacies
- Cosmetic piercers
- Zoo, safari parks, ...

6 Waste identification and classification; waste groups

33. The following classification of biomedical and healthcare waste is based on the major classification in the Annexes I, II, VIII and IX of Basel Convention, but specified for practical use in the healthcare sector. Therefore biomedical and healthcare waste is classified in the following Groups:

- A Healthcare wastes with similar composition to household and municipal waste
 - A1 Normal household and municipal waste
- B Biomedical and healthcare waste requiring special attention
 - B1 Human anatomical waste (tissues, organs, body parts, blood and blood bags))
 - B2 Waste sharps (needles, syringes, scalpels, slides, ampoules,)
 - B3 Pharmaceutical waste (e.g. out of date medicines)
 - B4 Cytotoxic pharmaceutical wastes
 - B5 Blood and body fluid waste (materials contaminated with blood or other body fluids, soiled cotton from non infected patients)
Wastes which only require special measurements to prevent infective risk during there management.
- C Infectious waste
For the purpose of these guidelines, infectious healthcare wastes^{▲)} are:
 - a) discarded materials or equipment contaminated with blood and its derivatives, other body fluids or excreta from infected patients with hazardous communicable diseases (specified in Chapter 6.1, No. 38). Contaminated waste from patients known to have blood borne infections undergoing haemodialysis (e.g. dialysis equipment such as tubing and filters; disposable sheets, linen, aprons, gloves or laboratory coats contaminated with blood).
 - b) Laboratory waste (cultures and stocks with any viable biological agents artificially cultivated to significantly elevated numbers incl. dishes and devices used to transfer, inoculate and mix cultures of infectious agents and infected animals from laboratories).
- D Other hazardous waste^{◆)}
Not exclusive to medical healthcare sector e.g. solvents, chemicals, batteries, fixer solutions,
- E Radioactive waste from healthcare

▲) The interpretation of the definition of infectious healthcare waste varies according to national circumstances, policies and regulations; other international organizations have specific interpretations of the definition (such as WHO, International Transport Regulation). Infectiousness is one of the hazard characteristics contained in Annex III to the Basel Convention and defined in H6.2. Further elaboration of the characteristics is the subject of working papers under discussion by the Technical Working Group.

◆) For further information the WHO-Guideline "Safe Management of Wastes from Healthcare Activities" is recommended.

6.1 Fact sheets

34. B1: Human anatomical waste

Description

Non-infectious human body parts, organs and tissues and blood bags.

Examples of such wastes

Tissue waste, removed organs, amputated body parts, placentas, etc..

Waste management guidance

It is above all for ethical reasons that special requirements must be placed on the management of waste human body parts, organs and tissue. The waste must be collected in appropriate containers or bags as soon as possible, and at the place where, it is generated. The waste must be kept in tight receptacles (e.g. in the wooden coffins commonly used in pathology) and under cooled conditions when stored temporarily for a prolonged period of time, or else be handed over to a waste management facility within a reasonable period. Intermediate storage takes place at a location which is only accessible to trained personnel. Normally the waste must always be incinerated completely, in an appropriate facility. Household waste incineration plants are, as a rule, are not suited for the incineration of amputated body parts, removed organs and placentas (cases of exceptions – like separate storage and direct feeding – have to be clarified with responsible authorities and management of the incineration plant).

In exceptional cases crematoria can be used for the incineration (disposal) of amputated body parts.

Exemptions and special provisions

Where only small quantities of these wastes are generated (e.g. medical practices), they can be collected in appropriate containers (e.g. "hard box") and managed jointly with municipal waste at a volume of up to 1 litre per waste bag.

The management of animal waste body parts, organs and tissues is subject to the provisions of relevant special legislation.

35. B2: Waste posing the risk of injury ("sharps")

Description

Sharps are all objects and materials which are closely linked with healthcare activities and pose a potential risk of injury and/or infection.

Examples of such wastes

Needles, drain tubes, syringes with the attached needle, butterfly needles, spikes, broken glassware, ampoules, pipettes, scalpel blades, lancets, vials without content, and the like.

Waste management guidance

Wastes posing the risk of injury require measures to be taken to prevent injury and infection during the handling of these wastes within and outside of healthcare establishments. These wastes have to be collected and managed separately from other waste. The collection containers must be puncture-resistant and leak-tight. Storage of these wastes takes place at a location which is only accessible to trained personnel.

Notice: Sharps from infected patients, isolated wards, infected patients undergoing haemodialysis or other pointed parts contaminated with laboratory waste must be categorised as infectious waste.

Exemptions and special provisions

Syringes and needles should not be re-used.

Notice: Some countries handle all sharps as infectious waste

36. B3: Pharmaceutical waste

Description

Pharmaceutical wastes are pharmaceuticals which have become unusable for the following reasons:

- expiration date exceeded;
- expiration date exceeded after the packaging has been opened or the ready-to-use preparation prepared by the user
- use is not possible for other reasons (e.g. call-back campaign)

Examples of such wastes

The term "pharmaceuticals" embraces a multitude of active ingredients and types of preparations. The spectrum ranges from teas through heavy metal containing disinfectants to highly specific medicines containing a large variety of different hazardous or non hazardous substances. Waste management may therefore be based on of a differentiated approach; for example pharmaceutical waste could be divided into three classes and their management be carried out in a class-specific manner:

- *Pharmaceutical wastes: Class 1*

Pharmaceuticals such as camomile tea, cough syrup, and the like, which pose no hazard during collection, intermediate storage and waste management.

Class 1 pharmaceutical wastes are not considered hazardous wastes. They are managed jointly with municipal waste.

- *Pharmaceutical wastes: Class 2*

Pharmaceuticals which pose a potential hazard when used improperly by unauthorised persons.

Class 2 pharmaceutical wastes are considered to be hazardous wastes. Their management takes place in an appropriate waste disposal facility.

- *Pharmaceutical wastes: Class 3*

Heavy metal containing and unidentifiable pharmaceuticals, heavy metal containing disinfectants, which owing to their composition require special management.

Class 3 pharmaceutical wastes are considered to be hazardous wastes. Their management takes place in an appropriate waste disposal facility.

However, due to the fact that medicines are not normally labeled in accordance with their hazardous characteristics, the sorting of medicines into different classes, in particular classes 2 and 3, may often be too difficult in practice. Therefore, countries may decide to

consider all or major part of medicines as hazardous waste or waste requiring special consideration.

Waste management guidance

Waste prevention: To reduce the generation of pharmaceutical waste, stocks of pharmaceuticals should be inspected periodically and checked for their durability (expiration date).

Recovery by specialised facilities: Possibilities for returning old pharmaceuticals to the producer or handing them over to a special collection system (e.g. pharmacies) for possible subsequent use could be explored. Such a return of pharmaceuticals in their original packaging prior to or within a reasonable period after the expiration date is possible if it is ensured that the producer or collector examines possibilities for a subsequent use of the pharmaceuticals and that pharmaceuticals which are no longer usable are disposed of in an environmentally sound manner.

Pharmaceutical wastes which are considered to be hazardous wastes have to be collected separately in appropriate containers. Intermediate storage takes place at a location which is only accessible to trained personnel. This should be done in a manner to avoid misuse.

Exemptions and special provisions

Cytotoxic pharmaceutical waste: See Group B4: Cytotoxic pharmaceutical waste

37. B4: Cytotoxic pharmaceutical wastes

Description

Cytotoxic (antineoplastic) pharmaceutical wastes are wastes which can arise by use (administration to patients), manufacture and preparation of pharmaceuticals with a cytotoxic (antineoplastic) effect. These chemical substances can be subdivided into six main groups: alkylated substances, antimetabolites, antibiotics, plant alkaloids, hormones, and others. A potential health risk to persons who handle cytotoxic pharmaceuticals results above all from the mutagenic, carcinogenic and teratogenic properties of these substances. Consequently, these wastes pose a hazard, and the measures to be taken must also include those required by occupational health and safety provisions.

Examples of such wastes

Specific lists of pharmaceuticals which contain cytotoxic substances are available. Discernible liquid residues of cytotoxic concentrates, post-expiration-date cytotoxic pharmaceuticals and materials proven to be visible contaminated by cytotoxic pharmaceuticals must be disposed of as cytotoxic pharmaceutical waste.

Waste management guidance

The risks posed by cytotoxic pharmaceuticals are primarily of relevance for persons which come into contact with them during preparation and during or after their use. It has long been common practice in hospitals to see to it that the circle of persons who come into contact with these products is small. Specific guidance on this is available. These wastes usually arise at central locations, i.e. in pharmacies and laboratories, and these often are also where the ready-to-use cytotoxic solutions are prepared. Intermediate storage of these wastes takes place under controlled and locked conditions.

The precautions taken during the use of cytotoxic pharmaceuticals must also be applied on their journey outside of the respective establishment, as releases of these products can have adverse environmental impacts. The management of these wastes, in covered and imperme-

able containers, must therefore be strictly controlled. Solid containers must be used for collection. The use of coded containers is recommended. For reasons of occupational safety, cytotoxic pharmaceutical wastes must be collected separately from pharmaceutical waste and disposed of in a hazardous waste incineration plant.

Exceptions and special provisions

None.

38. B5: Waste with blood and body fluid

Description

Wastes from health-care establishments not categorised as infectious waste which are contaminated with human or animal blood, secretions and excretions. It is warranted to assume that these wastes might be slightly contaminated with pathogens reasonable (nearly the same as household waste).

Examples of such wastes

Dressing material, swabs, syringes without the attached needle, infusion equipment without spike, bandages etc..

Waste management guidance

Special requirements must be imposed on the management of these waste from the viewpoint of infection prevention inside the healthcare establishments. Double bags or containers made of comparably strong and leak-proof material are used for the collection of these wastes within healthcare establishments.

Proper management of these wastes consists of incineration in a household waste incineration plant but can also be disposed together with household waste on a controlled landfill site. It should be noted that some countries prohibit the landfilling of waste with blood and body fluids.

Exemptions and special provisions

This mixture of wastes should not be recycled.

39. C: Infectious wastes^{♦)}

Description

Special requirements on the collection and management of infectious wastes must be imposed

-
- ♦) For the purpose of these guidelines, infectious healthcare wastes are:
- a) discarded materials or equipment contaminated with blood and its derivatives, other body fluids or excreta from infected patients with hazardous communicable diseases. Contaminated waste from patients known to have blood borne infections undergoing haemodialysis (e.g. dialysis equipment such as tubing and filters; disposable sheets, linen, aprons, gloves or laboratory coats contaminated with blood).
 - b) Laboratory waste (cultures and stocks with any viable biological agents artificially cultivated to significantly elevated numbers incl. dishes and devices used to transfer, inoculate and mix cultures of infectious agents and infected animals from laboratories).

(The interpretation of the definition of infectious healthcare waste varies according to national circumstances, policies and regulations; other international organizations have specific interpretations of the definition (such as WHO, International Transport Regulation). Infectiousness is one of the hazard characteristics contained in Annex III to the Basel Convention and defined in H 6.2. Further elaboration of the characteristics is the subject of working papers under discussion by the Technical Working Group.)

whenever waste is known or, based on medical experience, expected to be contaminated by causative agents of the diseases listed below and when this contamination gives cause for concern that the disease might spread. The list comprises diseases which, when taking into account

- the associated risk of infection (contagiousness, infection dose, epidemic potential),
- the viability of the pathogen (infection capacity/infectiousness),
- the route of transmission,
- the extent and nature of the potential contamination,
- the quantity of contaminated waste, as well as
- the severity and treatability of the disease that might be caused,

make particular demands on infection prevention.

Such wastes belonging to this group may occur in the context of diagnosis and treatment of patients suffering from the following diseases (relevant pathogen-containing excretions are given in brackets):

AIDS* (blood)

Viral hepatitis* (blood, faeces)

Creutzfeld-Jacob disease (CJD), transmissible spongiform encephalopathy (TSE)* (tissue, cerebrospinal fluid)

Cholera[#] (faeces, vomit)

Typhoid fever/Paratyphoid fever[#] (faeces, urine, bile)

Enteritis, dysentery, EHEC-induced haemolytic uraemic syndrome (HUS)[#] (faeces)

Active tuberculosis (respiratory tract secretions, urine, faeces)

Meningitis/encephalitis (respiratory tract secretions, cerebrospinal fluid)

Brucellosis (blood)

Diphtheria (respiratory tract secretions, secretions from infected wounds)

Leprosy (secretion from nose/infected wounds)

Anthrax (respiratory tract secretions, secretion from infected wounds)

Plague (respiratory tract secretions, secretion from infected wounds)

Poliomyelitis (respiratory tract secretions, faeces)

Q fever (respiratory tract secretions, blood, dust)

Glanders (respiratory tract secretions, secretion from infected wounds)

Rabies (respiratory tract secretions)

Tularemia (pus)

Virus-induced haemorrhagic fever including hantavirus-induced renal (HFRS) and pulmonary (HPS) syndromes (blood, respiratory tract secretions, secretion from infected wounds, urine)

Waste of this kind is typically generated in:

- isolation wards of hospitals,

- dialysis wards or centers caring for patients infected with hepatitis viruses (yellow dialysis),
- pathology departments,
- operating theatres,
- in medical practices and laboratories which mainly treat patients suffering from the diseases specified above.

The relevant wastes are wastes contaminated with pathogen-containing blood, excretions or secretions (see list) or containers containing blood in liquid form.

Examples

The infections marked with (*) are usually transmitted by inoculation. Therefore, the wastes of relevance here are not taken to include dry contaminated waste from sporadic patients suffering from respective diseases (AIDS, viral hepatitis, CJD), such as contaminated swabs (e.g. from taking of blood samples), cotton plugs used in dental practices, etc. They do include, however, blood-filled vessels and waste drenched with blood or secretions from surgeries performed on infected patients, used dialysis systems from yellow dialysis as well as wastes drenched with blood/secretions from medical practices and laboratories mainly treating patients who have contracted the diseases in question.

The infections marked with (#) are transmitted via faeces and oral ingestion of contaminated material. Relevant bodily discharges may be fed to the wastewater stream in observance of hygienic requirements.

Management under conditions that would result from categorisation as infectious waste must be considered only when the waste is heavily contaminated with excretions from diagnosed patients.

Infectious wastes in any case include the following:

- all microbiological cultures generated e.g. in institutes working in the fields of hygiene, microbiology and virology as well as in medical laboratories, medical practices and similar establishments and in which a multiplication of pathogens of any kind has occurred, and
- experimental animals as well as litter and animal faeces from animal test laboratories, if a transmission of the above-mentioned diseases is to be expected.

Waste management guidance

Infectious wastes must be collected in tear-resistant and leak-proof containers and transported to a central storage facility/delivery point in carefully sealed condition and without any transfer into other containers or sorting (containers marked with the "biohazard" symbol).

The wastes must be collected and transported in a way that precludes direct contact, and they may not be transferred into other containers at the central storage facility or during delivery. They must be stored in such a way that gas formation in the collection containers is avoided. To this end, efforts must be made to ensure that storage periods are as short as possible depending on climatic conditions (e.g. storage at temperatures below +15°C for not more than one week or at a temperature of 3°C to 8°C for a longer storage period).

Infectious waste must either be incinerated (approved incineration plant) or be disinfected prior to final disposal using a recognised method, preferably treatment with saturated live steam.

Disinfected wastes may be disposed of in the same way as domestic waste.

The disinfection plants must be operated under the operating parameters prescribed for waste disinfection and this mode of operation must be documented.

The use of a mobile disinfection plant to treat infectious waste is permissible only if the waste disposer furnishes proof that the plant has been checked by the competent authority or an approved institutions for its functional and operational reliability on a regular basis.

The efficiency of the vapour disinfection plant must be verified by a recognised institution when the plant is first put into operation and at regular intervals thereafter (e.g. twice a year), using appropriate microbiological indicators (see Annex IV).

Exceptions and special provisions

Body fluids and excreta of infected patients with hazardous communicable diseases can be discharged to the sewerage system if there is a strict separation between the waste and drinking water installations and the sewerage system is connected to waste water plant. In other cases the body fluids and excreta had to be disinfected before discharged to the sewerage system.

Only as an exception for developing countries infectious waste can be disposed of by using a special area in a controlled landfill if there is no risk for the contamination of ground or drinking water and the infectious waste is directly covered with earth or other material.

40. E: Radioactive Waste

Description

Material contaminated with a radio-isotope which arises from the medical or research use of radionuclides. It is produced, for example, during nuclear medicine, radio immunoassay and bacteriological procedures, and may be in a solid, liquid or gaseous form.

Examples of such wastes

Radioactive waste includes solid, liquid and gaseous waste contaminated with radionuclides generated from in vitro analysis of body tissue and fluid, in vivo body organ imaging and tumour localisation, and investigative and therapeutic procedures. Radioactive healthcare waste usually contains radionuclides of short half-lives like ^{32}P (β , 14.3 days half-life), ^{57}Co (β , 271 days half-life) or $^{99}\text{Tc}^{\text{m}}$ (γ , 14.3 days half-life) and loose their activity relatively quickly. Certain therapeutic procedures require the use of radionuclides with longer half-lives like ^{60}Co (β , 5.3 years half-life), ^{137}Cs (β , 30 years half-life) or ^{226}Ra (β , 1600 years half-life), which are usually conditioned as pins, pills or needles and may be reused on other patients after sterilisation.

Waste management guidance

Where activity limits for immediate or simple disposal methods cannot be met (clearance levels), healthcare establishments should segregate radioactive waste, and store during the required period to reduce the activity level. If the activity concentration is below these clearance levels, the material may be disposed of by normal methods. Guidance[♦] on clearance levels have been provided by the IAEA. Since the half-life of most radioactive materials used in hospitals is in the range of hours or days, storage for a period of one or two months can be

[♦] Clearance of materials resulting from the use of radionuclides in medicine, industry and research, IAEA-TECDOC-100 (1989)

followed by disposal to the ordinary waste system with appropriate monitoring. Decayed non-infectious radioactive waste is placed inside black plastic bags if they are intended for landfilling. Decayed but infectious radioactive wastes are placed in yellow plastic bags in view of their disinfection. They should not be landfilled prior to disinfection.

All radioactive waste designated for storage to allow decay, should be kept in suitable containers which prevent dispersion of the content. A plastic bag in a large can or drum is an appropriate container. Containers used for the storage of radioactive waste should be clearly labelled to show the radionuclide's activity on a given date, and period of storage required. These containers should be stored in a specifically marked area in a lead shielded storage room for radioactive substances or for radioactive waste. The storage record should be endorsed specifically to indicate the items which are "radioactive waste". Containers of radioactive waste should be marked "RADIOACTIVE WASTE" and should carry the radiation symbol.

High level and usually long half-life radionuclides used in healthcare activities are used for therapy purposes, conditioned as sealed sources, on the format of pills, seeds, ribbons, tubes or needles. These sealed sources are recovered after use, washed, disinfected and stored under lead-shielding in view of their further reuse on other patients. These items may however become waste if their conditioning is damaged, if they have lost too much of their activity, or if they are no longer required. Spent radionuclides generators also become waste. In countries without nuclear industry equipped to dispose of high level radioactive waste, hospitals should package these items appropriately, or place inside the same boxes in which they were originally supplied, and send them back to their original supplier for reprocessing, eventual recycling, or safe final disposal. In countries with the appropriate nuclear industry, hospitals may alternatively send non-recyclable high level waste to the national radioactive waste disposal agency, which will take care of them. These items are usually valuable, and in most cases it is possible to reprocess them in view of their recycling.

Exceptions and special provisions

Any healthcare establishment using radioactive substances, should hire a specialised radiation officer who among other duties, will monitor the management and disposal of radioactive waste and the storage of radioactive items.

7 Applicable state of the art management and treatment and disposal technologies

41. It is generally recognised that waste management plans provide the best mechanism for improvement in environmental performance in waste management. A waste management plan can assist generators conserve resources and minimise waste through improved purchasing and reuse practices and through cost effective, environmentally sound source separation, segregation, collection, transport, treatment and disposal of all wastes streams generated within their facilities.

42. It is recommended that the plan be in the form of an environmental management system based on the ISO 14001 series of environment management standards. This systems approach helps ensure auditable, verifiable documentation is available to demonstrate that operations are occurring as required. Such a system will also assist with provision of quality data and information on which a State of Environment report can be prepared.

43. A prerequisite to developing or updating such a plan is adequate characterisation and analysis of the existing waste stream and a detailed assessment of existing waste management practices. This process is commonly referred to as a Waste Audit.

7.1 Avoidance/Prevention

44. According to the principles of the Basel Convention, each Party shall take the appropriate measures to ensure that the generation of hazardous wastes and other wastes within it is reduced to a minimum and that adequate disposal facilities for the environmentally sound management of hazardous wastes and other wastes are available.

45. For the various healthcare establishments, waste management in observance of the waste avoidance and recovery obligation presupposes a system that is practice-oriented, clearly structured and manageable and clearly defined logistics. This can only be achieved if everyone who works in the health-services sector gives increased thought to this issue and acts so as to ensure that the volume and hazardousness of wastes are minimised.

46. The increasing relevance of the waste management problem demands an ecologically oriented reorganisation. This should already start in procurement, by giving preference to environmentally sounder products and replacing harm-

ful or disposable products with re-usable or alternative products, if these meet the relevant requirements in terms of hygiene and patient safety.

47. A noticeable reduction in waste volume can only be achieved if disposable products already in use are scrutinised as to their necessity. In principle, disposables such as

- disposable cutlery
- disposable linen (including covering sheets)
- disposable instruments and equipment (scissors, scalpels, forceps)
- disposable containers (kidney dishes, infusion bottles)

should be replaced by re-usable products and long-lived alternatives. For examples of specific reuse, waste reduction, and waste recycling activities see Annex III and the literature mentioned in the bibliography.

7.1.1 Packaging

48. An issue closely related to the procurement of products is their packaging. It is possible to noticeably reduce the amount of waste generated if attention is paid in the selection of products to the associated amount of packaging. The latter should not exceed the minimum necessary to meet transportation, storage, hygienic and sterility requirements. Before orders are placed, the material input for the product and the packaging as well as the resulting input required for waste management should be taken into account.

49. The input required for the management of packaging waste can be reduced

- when preference is given to products involving low amounts of packaging,
- when preference is given to product packaging which can be refilled, re-used or otherwise used as supply or disposal receptacle within or outside of the facility where it occurs,
- when preference is given to demand-oriented package sizes,
- when the manufacturer or supplier of the product is required, when placing the order, to take back the associated transport packaging and containers.

Where it cannot be avoided, packaging should be collected separately and fed to an appropriate recovery process. Appropriate recovery is common for card-

board, paper, glass and metals. Plastics can best be recovered if they are collected as type-specific fractions.

7.1.2 Kitchen and canteen waste

50. Kitchen and canteen waste can be utilised as feed substitute if it is disinfected in a manner which is appropriate for such use or if such use conforms with the conditions imposed by the authorities.

7.1.3 Laboratory waste and chemical residues

51. An effort must be made to assess which hazardous products and substances in the healthcare industry can be avoided completely. Chemical residues can be reduced by adapting laboratory apparatus to the "state of the art" and performing laboratory tests and analyses if they meet medical needs. In the procurement of laboratory devices, attention should be paid to the aspect of relative chemicals consumption.

52. One such pertinent example that has been targeted for elimination and future avoidance in many countries is the use of mercury containing hospital diagnostic devices such as blood pressure gauges and thermometers. Elemental mercury is toxic and such uses present hazards during use and at end-of-life. Mercury can neither be safely landfilled nor incinerated. Fortunately, safer alternatives now exist for each of these mercury-containing products. Thus the problem is best avoided in the first instance through procurement policies.

53. In the area of laboratory chemicals, a priority task is to examine whether the use of chlorinated hydrocarbons as solvents is unavoidable. The aim should be to convert such laboratory procedures. Laboratory chemicals and solvents should be collected and primarily recovered, if the cost recovery entailed is reasonable in comparison with that of other forms of waste management. The best possibilities for solvent-recovery exist in pathology, histology and anatomy, because relatively large amounts of fat and blood-contaminated solvents (xylene, toluene, and other) arise in these sectors.

7.2 Segregation, collection, labelling and handling of biomedical and healthcare waste

54. Segregation is the key to effective biomedical and healthcare waste management. It ensures that the correct disposal routes are taken, personnel safety is maintained, environmental harm is minimised and the least resources for recycling can be used. Biomedical and healthcare waste should be segregated and collected according to the specific treatment or disposal requirements.

55. Segregation should be done under the responsibility of the waste producer and as close as possible to the point of generation. Therefore segregation must take place at source, that is, on the ward, at the bedside, theatre, laboratory, delivery room, etc., and must be carried out by the person generating the waste for instance the nurse, doctor, specialist, etc., in order to immediately secure the waste and to avoid dangerous secondary sorting. Segregation should be undertaken on the basis of the types of waste listed in the definition for biomedical and healthcare waste.

56. Each healthcare institution should prepare and follow a waste plan. Correct and efficient segregation will only be achieved through rigorous training and education of employees, supervisors and managers. Policies should take this into account.

57. The same segregation system should be uniformly applied throughout the whole county. The segregation must be applied from the point of generation throughout the entire waste stream to the point of final disposal, whether or not it is on-site. All storage and transportation methods must also follow this segregation system.

58. Segregated wastes of different categories need to be collected in identifiable containers. Every room, such as ward, laboratory, operation theatre etc., should have containers/bags for the types of wastes that are generated in that room. The waste segregation and identification instructions should be placed at each waste collection point to ensure proper procedure. Waste containers made of non-halogenated leakproof combustible materials should always be given preference.

59. Plastic bags for storing the waste may be suspended inside a frame or be placed inside a sturdy container. A lid should be provided to cover the opening of the bag.

60. Sharps must always be collected in puncture-proof containers (not made of glass) to avoid injuries and infection to the workers handling them.

61. Clinical and sanitary personnel should ensure that the waste bags are removed and sealed when they are not more than three quarters full. The preferred method of sealing is with a plastic sealing tag of the self-locking type; bags should never be closed by stapling. Each bag should be labelled with the point of generation (ward and hospital) and content.

62. A common system of labelling and coding of packaging should be developed for biomedical and healthcare waste. A possible way of identifying the biomedical and healthcare waste categories is by sorting it into colour coded bags or containers. As an example a WHO recommended colour coding is given in table 2. The use of internationally recognised symbols and signs is very basic and is essential for the safety of handling and disposal of waste. It is recommended that the colour coding, the symbols and signs are part of the waste management instructions and made known e. g. by poster on the wall at the waste collection points.

Table 2: WHO Recommended colour coding for biomedical and healthcare waste as an example for a colour coding system

| Type of waste | Colour of container and markings ^{*)} | Type of container |
|---------------------------------------------------------|------------------------------------------------|--------------------------------------------------------------------------|
| Highly infectious waste | Yellow, marked "HIGHLY INFECTIOUS" | Strong, leak-proof plastic bag, or container capable of being autoclaved |
| Other infectious waste, pathological and anatomic waste | Yellow | Plastic bag or containers |
| Sharps | Yellow, marked "SHARPS" | Puncture-proof containers |
| Chemical and pharmaceutical waste | Brown | Plastic bag or container |
| Radioactive waste ^{**)} | - | Lead box, labelled with the radioactive symbol |
| General healthcare waste | Black | Plastic bags |

^{*)} Proposed colour coding and marking system; the use of other colour coding in a country is possible.

^{**)} Only generated in major hospitals

63. Certain recommendations should be followed by the ancillary workers in charge of waste collection:

- Waste should be collected daily from the wards, or as frequently as required, and transported to the central storage place;

- No bags should be removed without labelling containing point of generation (hospital and ward) and content;
- The workers should immediately replace the bags or containers with new ones of the same type.

Empty collection bags or containers should be readily available at that location of waste generation.

7.3 In-house Transport and Storage

64. It is important to ensure that waste does not accumulate at the point of generation. A routine for the collection of waste should be established in the waste management plan. Wastes should be moved through the facility in such a manner as to prevent unnecessary exposure to staff and others. The handling and transport of waste containers should be minimised to reduce the likelihood of exposure to the waste. Specific routes must be planned through the facility to minimise the passage of loaded carts through patient care and other clean areas.

65. Carts used for moving biomedical and healthcare waste through the healthcare facility should be designed to prevent spills, and made of materials able to withstand exposure to common cleaning agents. They should have the following attributes:

- Easy loading and deloading;
- No sharp edges which could damage waste bags or containers during loading and deloading;
- Easy to clean.

All seals should be in place when movement of the bag has been completed.

66. The carts should be cleaned regularly to prevent odour and as soon as possible if the waste material leaks or spills in the carts. The biohazard symbol should be clearly displayed on carts for the transport of infectious waste. These carts must be thoroughly cleaned before any maintenance work is performed on them. The facility's infection control committee, biosafety officer, or other appointed person should be consulted about the frequency of cleaning and the type of cleaning agent to be used.

67. After biomedical and healthcare waste has been collected and moved from the point of generation, it must be held in storage areas to await disposal. These storage areas, either a separate area, room or building, should be dimensioned according to the generated waste quantities and frequency of collection.

These areas must be totally enclosed, and separate from supply rooms or food preparation areas. Recommendations for properties and equipment of the storage facilities are listed in box 1.

68. Storage areas must be identified as containing infectious waste, with the biohazard symbol clearly displayed. It is unacceptable for materials other than waste to be placed in the same storage area as infectious waste. Floors, walls, and ceilings of storage areas must be thoroughly cleaned in accordance with the facility's established procedures. These procedures should be prepared in consultation with the facility's infection control committee, biosafety officer, or other appointed person.

Box 1: Recommendations for storage facilities for biomedical and healthcare waste in healthcare establishments, e.g. hospitals

Properties and equipment

- Impermeable hard-standing base with good drainage, easy to clean and disinfect, and equipped with water-supply;
- Readily accessible to staff in charge of handling the waste;
- Fitted with a lock, e.g. to prevent access by unauthorised persons;
- Easily accessible for collection vehicles (carts);
- Inaccessible for animals, insects and birds;
- Good lighting and ventilation;
- Not situated in proximity of fresh food stores or food preparation areas;
- Situated close to supply of cleaning equipment, protective clothing and waste bags or containers.

69. The proposed storage periods recommended by WHO between generation and treatment of biomedical and healthcare waste are the following, unless a cooled storage room is available:

Temperate climate: maximum 72 hours in winter
 maximum 48 hours in summer

Warm climate: maximum 48 hours during the cool season
 maximum 24 hours during the hot season

Anatomical waste should be stored at a temperature of 3° C to 8° C. All infectious waste must be refrigerated at a temperature of 3° C to 8° C if stored for more than a week. Healthcare facilities should determine the maximum storage time of refrigerated or frozen biomedical and healthcare waste based

upon its storage capacity, rate of waste generation, and any applicable local regulatory requirements.

70. Facilities refrigerating or freezing stored waste should use a lockable, closed storage facility or a lockable domestic type freezer unit. Either type must be used only for storing anatomical and infectious waste, visible display the biohazard symbol, and be identified as containing infectious waste. Notice that glass or plastic items containing infectious agents may fractures at lower temperature.

71. The compacting of untreated infectious waste or of waste with a high content of blood or other body fluids (risk of spilling) destined for off-site disposal is not permitted.

72. Cytotoxic waste should be stored in a specific place, separate from the storage room devoted to other biomedical and healthcare waste.

73. Depending on the local legislation radioactive waste should be stored in containers preventing from dispersion, behind lead shielding. Waste designated for storage to allow decay should be labelled with the type of radionuclide, date and required storage details.

7.4 Special requirements for packaging and labelling for off-site transport

74. Risks may occur during the storage, handling, transportation and disposal of the infectious waste. Therefore biomedical and healthcare waste generators are responsible for safe packaging, adequate labelling and authorisation of the destination of the waste to be transported off-site. Hazardous biomedical and healthcare waste should be packaged and labelled to comply with national regulations regarding the transport of hazardous wastes (dangerous goods), and with international agreements if they are shipped abroad for treatment. In case there are no such national regulations, responsible authorities may refer to the "Recommendations on the transport of dangerous goods by road (class 6, deviation 6.2, UN No. 3291)" published by the United Nations.

75. The control strategy for hazardous biomedical and healthcare waste shall have the following components:

- A consignment note should accompany the waste from production to final disposal; after the journey, the transporter should complete the part of the consignment note especially reserved for him and return it to the generator;

- The transporting organisation should be registered with, or known to, the waste regulation authority;
- Handling and disposal facilities should hold a permit issued by a waste regulation authority, allowing the facilities to handle and dispose of hazardous biomedical and healthcare waste.

The consignment note should be designed taking into account the waste control system in operation in the country within the Basel Form.

76. Anyone involved in biomedical and healthcare waste generation, handling or disposal should be subject to a general "duty of care", i.e. ensure that documentation and transmission of waste comply with the national regulations.

7.4.1 Packaging requirements

77. In general the waste should be packaged in resistant and sealed bags or containers to prevent spilling during handling and transportation. The bags or containers should be resistant to their content (puncture-proof for sharps, resistance to aggressive chemicals) and to normal conditions of handling and transportation, such as vibration, changes in temperature, humidity or pressure (resulting from altitude for example). In the UN-Recommendation for the Transport of Dangerous Goods "infectious substances" (No. 2.6.3.1.1 UN Recommendation) are described as those substances known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) or recombinant micro-organisms (hybrid or mutant), that are known or reasonable expected to cause infectious disease in animals or humans.

78. Substances are not subject to the requirements of this UN-Division 6.2 if they are unlikely to cause human or animal disease. Most of the infectious wastes from healthcare establishments are wastes derived from the medical treatment of animal or humans or from bio-research. These wastes are mostly transported under UN 3291. Waste from infectious substances which can be specified (e.g. laboratory waste) shall be assigned to UN 2814 or UN 2900. Decontaminated wastes which previously contained infectious substances are considered non dangerous unless the criteria of another class are met.

79. According to the United Nations packing instructions for infectious substances, the packaging should include the following essential elements:

- An inner packaging comprising:

- watertight primary receptacle of metal or plastics with leakproof seal (e.g. a heat seal, a skirted stopper or a metal crimp seal);
 - a watertight secondary packaging;
 - absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle and the secondary packaging; if several primary receptacles are placed in a single secondary packaging, they shall be individually wrapped so as to prevent contact between them.
- An outer packaging of adequate strength for its capacity, mass, and intended use, and with a minimum external dimension of 100 mm.

7.4.2 Labelling

80. All waste bags or containers should be identified by labels containing basic information on producer and content. This information may be directly written on the bag or container or by pre-printed labels. According to the United Nations recommendations, the following indications should appear on the label:

- The United Nations substance class, e.g. class 6, division 6.2, UN No. 3291 for infectious waste;
- The United Nations label for class 6, division 6.2;
- The proper shipping name;
- The total quantity of waste covered by the description (by mass or volume);
- The packaging should be appropriately marked with the month and the last two digits of the year of manufacture;
- The country authorising the allocation of the mark, indicated by the distinguishing sign for motor vehicles in international traffic.

7.5 Recycling/Recovery

81. Recovery and recycling is one step in a systematic priority approach for environmental sound waste management. Waste segregation at source is the basic requirement for cost effective normal recycling operations on the non-hazardous component of biomedical and healthcare waste. Some examples for the recycling of non-hazardous waste components are given in Annex III.

82. Opportunities for chemical waste recycling can be described as follows:

- unused or waste chemicals in quantity can often be returned to the supplier for reprocessing,
- larger healthcare facilities should establish an internal reuse of chemicals,
- certain material such as mercury from broken thermometers and unused batteries containing mercury, cadmium, nickel and lead-acid and halogenated or non-halogenated solvents should be given to specialised recyclers.

7.6 Disposal operation/technologies, accreditation and environmental impacts

83. Biomedical and healthcare waste should, if required, be inactivated or rendered safe before final disposal or discharge. The decision to treat biomedical and healthcare waste and choice of treatment method should be determined in accordance with the following considerations:

- the type and nature of the waste material;
- the hazard and viability of the organisms in the waste;
- the efficiency of the treatment method;
- the operating conditions of the treatment method.

Table 3: Examples of waste treatment methods related to the type of waste

| Type of waste | Gas | Liquid | Solid |
|---------------|------------------|-------------------|-------------------|
| Thermal | X ¹⁾ | XXX ³⁾ | XXX |
| Chemical | XX ²⁾ | XX | X ⁵⁾ |
| Irradiation | (X) | (X) | (X) |
| Incineration | XX | XX ⁴⁾ | XXX |
| Filtration | XXX | X | N/A ⁶⁾ |

¹⁾ X possible ²⁾ XX appropriate ³⁾ XXX recommended (X) only for little amounts of waste

⁴⁾ recommended if the calorific value is high enough to reach a sufficient high temperature

⁵⁾ not possible for mixed wastes ⁶⁾ N/A not applicable

84. The treatment method should be amenable to validation, should be independent of any packaging and should be monitored. Monitoring can involve

sampling and analysis or testing of the effluent for hazardous organisms or the use of suitable physical engineering or other process controls to demonstrate effective operation within the prescribed operating criteria.

85. Treatment of the waste should be validated with regard to the inactivation of the organisms and the inactivation of any residual contamination of the packaging or containers. The process should not significantly increase the risk of exposure of laboratory staff or other waste handlers to the hazard itself or to other risks from the concomitant hazardous agents, equipment and substances which are employed in the treatment. Outlines of the main advantages and drawbacks of the treatment and disposal options addressed in this guideline are shown in table 4.

7.6.1 Treatment/disposal methods

86. The validated chemical and physical methods for the treatment or inactivation of waste include:

- steam sterilisation;
- chemical disinfection/sterilisation;
- dry heat sterilisation;
- other methods.

87. The relative effectiveness of these and other treatment methods depends on a number of factors including the volume, concentration, type and hazard caused by the organisms (and the physiological state, the diffusion resistance of the material to be disinfected and the operating parameters and conditions of the treatment method. In general, steam sterilisation should be preferably used in the treatment of infectious waste. Thermal methods are generally easier to validate and monitor than chemical treatment and are less damaging to the environment. An example for validation of waste disinfecting processes are given in Annex IV.

88. Methods other than steam sterilisation should be selected only if this is impracticable or inappropriate. For example, effluent from veterinary research, contaminated laboratory equipment, fixtures and furniture which cannot readily be removed may be effectively treated using a gaseous fumigant such as formaldehyde. These methods of treatment can be used alone or in combination, dependent on the risk assessment requirements and/or discharge consent standards, to enable the waste to be inactivated and safely discharged.

Table 4: Summary of main advantages and drawbacks of treatment and disposal options

| Treatment/disposal methods | Advantages | Drawbacks |
|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Pyrolytic incineration/two staged incineration with an efficient gas cleaning | Very high disinfection efficiency; Adequate for all infectious waste, and most of pharmaceutical and chemical waste. | Incineration temperature above 800°C Destruction of cytotoxics; Relatively high costs of investment and operation. Care has to be taken on the management of the incineration residues (e.g. bottom ashes, fly ashes) because they can exhibit hazard characteristics. |
| Single chamber incineration with dust reduction | Good disinfection efficiency; Drastic reduction of weight and volume of waste; The residues may be disposed on a landfill; No need for highly qualified operators; Relatively low investment and operation costs. | Generation of significant emissions of atmospheric pollutants and periodic slag and soot removal; With temperature below 800°C inefficient in destruction of thermally resistant chemicals and drugs such as cytotoxics. |
| Drum or brick incinerator | Reduction of weight and volume of the waste; The residues may be disposed on a landfill; No need for highly qualified operators; Very low investment and operating costs. | Only 99% destruction of micro-organisms; No complete destruction of many chemicals and pharmaceuticals; Massive emission of black smoke, flying ashes and toxic flue gas. Exception only for disposal of infectious waste under certain circumstances outside urban areas (e.g. no other treatment method available during emergency situation like acute outbreak of communicable diseases). |
| Chemical disinfection | Efficient disinfection under good operating conditions with special waste; Costly if the chemical disinfectants are expensive. | Requirement of highly qualified technicians for operation of the process; Use of hazardous substances which require comprehensive safety measures; Inadequate for pharmaceutical, chemical and most types of infectious waste (mixed solid waste). |
| Autoclave wet-thermal treatment | Environmentally sound ; Relatively low investment and operation costs. Good for infectiuo and microbiological wastes. | Shredding are subjected to many breakdowns and bad functioning; Operation requires qualified technicians; Inadequate for pharmaceutical and chemical waste or waste which not easily penetrable by steam; Without shredding or other destruction although inadequate for anatomic waste. |
| Microwave irradiation | Good disinfection efficiency under <u>appropriate operational conditions</u> ; Environmentally sound. | High investment and operation costs; Potential operation and maintenance problems; Only for wet infectious waste or for infectious waste with a high water content. |
| Encapsulation (e.g. with concrete, gypsum, ...) | Simple and safe; Low costs; | Only for sharps. |
| Special Engineered Landfill | Safe if access is restricted and where natural infiltration is limited | Safe if access of site is limited and there is no risk for water contamination |

7.6.1.1 Steam sterilisation

89. Steam sterilising or autoclaving is the exposure of waste to saturated steam under pressure in a pressure vessel or autoclave. Autoclaves should meet the requirements of internationally agreed standards. Autoclavable waste containers should be of a design and material which allows steam to penetrate the load. They should have sufficient stability and resistance to the maximum operating temperature and pressure.

90. In addition to any devices such as gauges or indicators which measure and record the basic operating criteria (e. g. temperature, vacuum, pressure), a biological or chemical indicator should be placed in the waste load for validation to indicate that the necessary sterilisation conditions have been achieved. The operational parameters, e. g. time, pressure and temperature, should be maintained and checked during the sterilisation cycle.

91. While the temperature and time depend upon the total volume of the material to be treated, the number and type of organisms and their resistance against steam, it is necessary first to remove all of the air from the autoclave, the waste and waste containers to ensure that the required sterilisation temperature will be maintained. In the case of closed containers included in waste material, the validation (with biological indicators) should take place within the material being sterilised. Sterilisation should only commence when the air has been removed from the autoclave and the operating temperature has been reached.

92. The potential of complete air removal is affected by factors such as the type of waste, the amount of waste, the packaging, the water content of the waste, and the form and material of the container. The whole treatment process including loading, the load, suitability of packaging or container, air removal and filtration of the removing gas and liquid effluent discharge should be validated.

93. A record should be retained of all monitoring, maintenance and performance tests carried out on the autoclave together with a logbook or similar record of all routine disposals including the temperature charts and details of the load. When appropriate, air removed from the autoclave should be discharged into the environment after passing through a microbiologically validated filter.

94. Details of sterilisation procedures, including the operational parameters and conditions, should be written down as a standard operating procedure document or operating manual which is to be used by all waste handlers. The document should be kept under review. A suitable biological indicator for steam sterilisation is the spores of *Bacillus stearothermophilus*. Autoclaving may not change the visible appearance of the waste and it may be necessary to distinguish treated from untreated waste by careful removal or obliteration of bio-

hazard warning labels from treated containers or by labelling such containers as "autoclaved" or "sterilised".

95. Alternatively, chemical indicators may be added to the load to indicate that the load has been autoclaved. Aesthetic concerns may require that the autoclaved waste is further treated to render it acceptable for final disposal, e.g. if the waste contains human or animal material or tissue. Autoclaving may not remove or reduce the non-biological hazards arising from the presence of chemical or physical agents or other materials in the waste.

7.6.1.2 Dry heat sterilisation

96. Dry heat sterilisation is the exposure of the waste to heat at a temperature and for a time sufficient to ensure sterilisation of the entire waste load. The sterilisation process should be monitored by the addition of a suitable indicator or measuring device to the waste load and where appropriate by monitoring the organism(s) present in the waste. The sterilising unit or equipment should incorporate a suitable thermal cut-out device which is independent of the temperature indicating or monitoring device.

7.6.1.3. Chemical disinfection/sterilisation

97. This method involves the exposure of waste to chemical agents which possess antimicrobial activity. General disinfectants may not inactivate organisms such as spores, some fungi and viruses and should not be used as the principle treatment methods unless thermal procedures are inappropriate because of the nature of waste of contaminated material. Thermal sterilisation should be given preference above chemical disinfection for reasons of efficiency and environmental considerations.

98. The choice of an appropriate chemical agent and conditions of use should be determined by the risk assessment taking into account the identity of the organism(s) to be treated, the nature of the waste and the presence of organic, protein or particulate matter and the nature of the surfaces, items or equipment which will be exposed to the chemical disinfectant.

99. Chemical agents should be used at the manufacturers' recommended concentrations and exposure times according to the requirements and conditions of use. The chemical agent selected should be compatible with other substances or material that may be present in the waste load so that its efficiency is not reduced and also to ensure that toxic or hazardous products are not thereby formed nor released. The efficiency of any chemical agent against a particular

organism or types of organism may be confirmed by reference and adherence to manufacturers' data and instructions. Ethylene oxide, formaldehyde (alone or with low temperature steam) and certain other agents may be used as gaseous fumigants particularly for equipment and items that should be treated in situ. This method can also be used for the disinfection of body fluids and excreta before given to the sewer system, if no thermal treatment is available.

7.6.1.4. Other treatment/disposal methods

100. The options available for the Treatment/disposal of waste and waste effluent which cannot be recycled or re-used are:

- incineration;
- landfill.

101. Other waste treatment methods are available but are not yet validated for general use and have only limited application. These include:

- irradiation (e. g. with microwave, gamma and ultraviolet radiation);
- other treatment methods (e. g. encapsulation and filtration).

If such methods are used, validation and monitoring procedures should be performed.

102. The selection of an appropriate option should be based on a number of considerations including:

- the nature of the waste itself and its intrinsic hazard;
- whether the waste has been inactivated by a reliable and validated method;
- the aesthetic acceptability of the discharged waste;
- the potential deleterious effect of the discharged waste on the environment;
- the ease and reliability of the disposal method;
- the disposal and other costs;
- the general occupational hazards and risks to waste producers, handlers and operators; and
- the overall impact of the disposal or discharge plant or equipment on the local and general environment.

7.6.1.5 Incineration

103. Incineration can be used as one important method for the treatment and decontamination of biomedical and healthcare waste. Oxidation at high temperature converts the organic compounds into their gaseous oxides, mainly carbon dioxide and water. Inorganic components are mineralised and converted into ash, unless they pass into the flue gas.

104. Depending on the type of incinerator the following objectives can be achieved:

- destruction of pathogens,
- reduction of the hazard and pollution potentials as far as possible,
- reduction of volume and quantity,
- conversion of remaining residues into a form which is utilisable or suitable for landfill,
- use of the released heat.

105. For reasons of emission control and operational safety and reliability, it is desirable to incinerate the biomedical and healthcare waste from as many hospitals as possible in one central unit. In specific cases, even smaller separate incinerators may be justified. With a view minimising the environmental impact of incineration plants, emissions in the air, water and soil shall be reduced by the use of effective and advanced incineration and emission control technique under technically and economically viable conditions taking into account the location of the plant.

106. Many industrial experiences in the implementation of techniques for the reduction of polluting emissions from incineration plants have been acquired over a period of more than ten years. As an example for high standards the emission limit values for waste incineration in the European Union which have been published at the end of 2000 are shown in table 7 in Annex V. Apart from these polluting emissions, all incinerators will produce varying amounts of residues e.g. bottom ashes, or fly ashes and particulate captured by pollution control devices. In the case they exhibit hazard characteristics these will likely need to be handled as additional hazardous wastes with appropriate environmentally sound disposal methods.

107. Incineration leads to a significant reduction of the volume and the quantity of the treated waste. Waste which has not been previously treated to inactivate it or to render it safe should be incinerated in a plant suitability designed and operated for the destruction of biomedical and healthcare waste or other hazardous waste. If biomedical and healthcare waste can only be incinerated under insufficient conditions (low temperature, inadequate emission con-

trol system) waste fractions like cytotoxic drugs, chemicals, halogenated materials or waste with a high content of heavy metals (batteries, broken mercury thermometers, ...) should not be given to such an incinerator.

108. Biomedical and hazardous (infectious) healthcare waste which has not been inactivated or treated should be conveyed or transported to the incinerator in suitable containers in accordance with the UN Recommendations on the Transport of Dangerous Goods by Road where appropriate.

Testing and validation of waste treatment methods

109. The selected treatment option is required to inactivate or render safe the hazardous component of the waste as relating to the risk assessment. It should be possible to validate the treatment method to verify that the number of viable organisms in any waste or effluent are within acceptable discharge levels or that the organism is destroyed.

110. Any treatment process for infectious waste has to be controlled for its efficiency. Where the waste treatment method is one that conforms to an appropriate international or national standard, its validation will be dependent on the strict adherence to specified procedures including any operational sampling, monitoring and performance tests undertaken to confirm that the treatment process proceeds as intended. These should be carried out in the prescribed manner and the required time intervals and a record of the relevant measurements and test parameters should be kept. Validation of any waste treatment process may also involve the periodic checking by verification tests for the presence of viable organism(s) in the waste. Appropriate statistical methods can be used to make inferences from these tests to overcome difficulties in verifying that the treated waste or effluent contains zero viable organisms.

111. Where a range of wastes from different sources and other characteristics are encountered, the treatment method should be validated for operational effectiveness under "worst case" load conditions. The operational conditions and parameters necessary to inactivate the "worst case" load should be used as the basis to define the normal operational procedures for mixed wastes. Tests carried out to check the concentration of viable organisms in the treated waste may be either growth related or non-growth related.

112. The method chosen will depend on the composition of the waste. For example, direct methods (see Annex IV) may be appropriate for testing waste streams with a low concentration of viable micro-organisms and indirect methods (see Annex IV) where the concentration is high.

Testing of treated waste and waste effluent

113. The efficiency of the treatment method can be checked by assaying the waste before and after treatment for the presence of viable organisms. Samples of the treated waste to be assayed should be taken from different parts of the load for examination under aseptic conditions.

114. Effluent from waste treatment processes which is discharged directly to air or the sewer system should be periodically tested as required by the relevant National or local consent authorities or to ensure the numbers of organisms are within permitted levels and there is no significant environmental risk.

115. The test methods and procedures used to assay treated wastes for the presence of viable organisms should be undertaken in accordance with international or national standards. Details of viability testing methods are available in standard reference texts^{^)}. Testing of waste discharge and effluent from treatment plant or equipment may be carried out continuously, or at periodic or irregular intervals, e.g., as random quality control checks. Tests would be carried out at frequent intervals if there is a likelihood of plant malfunction which would release untreated waste to the environment or if the plant is operating at or very near to capacity. In cases where biological indicators are less resistant than the organism that is being handled, the organism itself should be used as the test model.

Calibration of measuring and monitoring devices and equipment

116. All devices and equipment used to measure or monitor the performance of the treatment process or any discharges or emissions from any process should be calibrated. This can be done using an appropriate international or national standard test or by a method which employs an independent or reference test device or probe which is calibrated against a national standard.

117. Micro-organisms are classified with respect to human health and harm to the environment according to national or international classification schemes. A documented risk assessment should be made for the hazardous waste handling activities and treatment processes taking account of the classification of the micro-organisms that are involved. The assessment should be reviewed and revised, if necessary, at the different stages of the process design and implementation, if significant changes in the process are proposed and at periodic intervals.

^{^)} See Annex IV

118. In the case of activities involving exposure to several categories of micro-organisms which may be present in the waste, the health and environmental hazards presented by each micro-organism should be taken into consideration while preparing the assessment.

7.6.1.6 Landfill

119. To date there is no adequate risk assessment of the use of landfills for untreated biomedical and healthcare waste which may contain infectious organisms and hazardous chemicals. Best practice would require that any landfill used for biomedical and healthcare wastes be engineered and secured (specially engineered landfill).

120. There are ongoing health and safety issues (and hence legal implications) associated with disposal of untreated biomedical and healthcare wastes. With the availability of suitable landfill sites being reduced, the physical problem of disposing of large volumes of waste must be considered.

121. Disposing of infectious wastes to landfill greatly increases the risks to human health and the environment of exposure to infection from this source. If the waste is disturbed by any means, or not properly covered, further risks will arise. It is therefore not good practice to dispose of infectious waste direct to landfill. To guard against these risks, where landfill is the only available option, infectious wastes should be treated to destroy/remove their infectivity, preferably at the site of generation of the waste. This can be done by using known effective techniques such as autoclaving, microwave treatment, dry heat sterilization or chemical disinfection.

122. The following is a description of the features of an "specially engineered landfill^{*)}" which are necessary for the safe and environmentally acceptable disposal of biomedical and healthcare wastes:

- impermeable clay and or synthetic liner to minimise ground water pollution;
- collection, treatment and environmentally acceptable disposal of leachate;
- monitoring systems for ground water surrounding the site to check integrity of leachate contamination protection;
- daily and final covers to restrict the potential for disease vectors, reduce odours, and reduce water infiltration; and

^{*)} For further information see "Technical Guidelines on Specially Engineered Landfill (D5)"

- monitoring for gas migration in the unsaturated zone surrounding the site, together with control measures if necessary.

123. It is generally accepted that untreated biomedical and infectious healthcare waste disposal into landfills is not “Best practice”. Where healthcare waste are disposed of at a special engineered landfill site, the following should apply:

- biomedical and infectious healthcare wastes should be deposited at the lowest edge of the working face of the landfill or in a excavation;
- an operator or representative should supervise immediate cover with solid waste or cover soil to a depth of at least 1 metre;
- any compacting should only be on cover material;
- biomedical and healthcare disposal areas should be at least 3 metres from the proposed edge of the landfill;
- no access of unauthorized person to landfill site; and
- any biomedical and healthcare waste should be at least 2 metres below final surface of landfill i.e. not in final lift.

In accordance with national regulations and policies, landfilling may be prohibited in some countries.

124. The following biomedical and hazardous healthcare wastes are generally considered as not suitable for disposal at a landfill site:

- identifiable body tissue;
- cytotoxic wastes;
- pharmaceutical, laboratory or domestic chemicals;
- radioactive wastes;
- infectious wastes.

125. Landfill is recognised as the terminal site for all wastes including ash from incineration and residues from other processes. Some treatment process residues may contain chemicals which could interact with other materials in a landfill. Consideration needs to be given to the stability and nature of such process residues and any potential impacts prior to disposal to landfill. Some of these processes may also contribute excess water to the landfill. Resultant leachate considerations require that engineered landfills should be used to ensure maximum environmental protection.

Table 5: Overview of disposal and treatment methods suitable for hazardous healthcare waste categories

| Method | Pyrolytic incineration/two staged incineration (with afterburning zone, e.g. rotary kiln) | Single chamber incineration or municipal waste incineration | Chemical disinfection | Autoclave wet-thermal treatment | Microwave irradiation | Encapsulation (e.g. with concrete, gypsum, ... - only minimal programmes) | Specilally Engineered Landfill [*]) | Discharge to the sewer premises | Other method |
|----------------------------------|-------------------------------------------------------------------------------------------|-------------------------------------------------------------|-----------------------|---------------------------------|-----------------------|---------------------------------------------------------------------------|-------------------------------------------------------------------|-----------------------------------------------------|--------------------------------------------|
| Waste types | | | | | | | | | |
| Infectious waste | yes | yes (special requirements, like direct feeding) | small quantities | yes | Yes (wet waste) | no | (yes) | (no) only urine and faeces | |
| Anatomic | yes | (yes) | no | (no) | (no) | no | (yes) | no | |
| Sharps | yes | (yes) | yes | yes | no | yes | (yes) | no | |
| Pharmaceutical waste | small quantities or at high temperature >850 °C | (yes) | no | no | no | yes | small quantities | no | return expired drugs to supplier |
| Cytotoxic waste | at high temperature >850 °C | no | no | no | no | no | in exeptional cases if special requirements like fixation are met | no | return expired drugs to supplier |
| Chemical waste | small quantities | (no) | no | no | no | no | in exeptional cases if special requirements like fixation are met | (yes) only small quantities of liquid disinfections | return unused chemicals to supplier |
| Radioactive waste ^{**)} | low-level infectious waste | low-level infectious waste | no | no | no | no | no | low-level liquid waste | decay by storage |

Bold and italic: preferred method

^{*}) In accordance with national regulations and policies, landfilling may be prohibited in some countries

^{**)} Only if the clearance levels provided by the IAEA are met

126. The application of treatment and disposal methods to biomedical and hazardous healthcare waste categories is shown in Table 6. It provides a broad overview of suitable treatment and disposal methods for the different healthcare waste categories.

7.7 Responsibility (including emergency response and contingency plan)

7.7.1 Assignment of responsibilities

127. The proper management of biomedical and healthcare waste is largely dependent on good administration and organisation. These should be supported by adequate legislation and financing, as well as active participation of trained and informed staff.

129. The head of the hospital should establish a waste management team to develop a waste management plan. The head of the establishment shall formally appoint the members of the waste management team in writing, informing each of them of their duties and responsibilities as outlined below.

130. In institutions where no direct patient care service is available, such as medical research institutions, the head of the establishment shall use his discretion to appoint members of the waste management team, based on the availability of relevant staff, the waste management officer's post may be assigned to the hospital engineer, to the hospital manager, or to any other appropriate staff, at the discretion of the head of the hospital.

7.7.1.1 Duties of the head of the hospital

131. The head of the healthcare establishment is responsible for the following tasks:

- Form a waste management team to formulate a written waste management plan for this hospital; within this plan, the duties and responsibilities of all members of staff, both clinical and non-clinical, shall be clearly defined in respect of the handling of healthcare waste. Clear line of accountability shall be indicated in both the clinical and non-clinical management structures;
- Designate the waste management officer (WMO) to supervise and co-ordinate the waste management plan; such an appointment shall not relieve him of his overall responsibilities in ensuring that biomedical and health-

care and other waste are disposed of in accordance with the national guidelines;

- Keep the management plan up to date;
- Allocate sufficient financial and manpower resources to ensure efficient operation of the plan; e.g., he has to ensure that adequate manpower is assigned to the waste management officer to ensure efficient operation of the waste management plan;
- Ensure that monitoring procedures are incorporated to assess the efficiency and effectiveness of the disposal system to effect the continuous improvement and updating of the system where appropriate;
- Immediately appoint a successor in the event of personnel leaving key positions in the waste management team, or temporarily assign responsibility until a successor is appointed;
- Ensure adequate training for key staff members; he shall designate staff responsible for co-ordinating and implementing training courses;
- Ensure adequate emergency response planning.

7.7.1.2 Duties of the waste management officer (WMO)

132. The WMO is responsible for day to day operation and monitoring of the waste management system. He or she shall have direct access to all members of hospital staff to facilitate his control function. The WMO will be directly responsible to the head of the hospital. He or she shall liaise with the Infection Control Officer, the pharmaceutical Officer and the Radiation Protection Officer to familiarise himself with the correct procedures for handling and disposing of pathological, pharmaceutical, chemical and radiological wastes.

133. Concerning waste collection, the WMO should undertake the following tasks:

- Control internal collection of waste containers and of their transport to the central waste storage facility of the hospital, on a day to day basis;
- Ensure supply of items required for waste collection and handling; he or she should liaise with the supplies department to ensure that an appropriate and acceptable range of healthcare waste bags and containers, protective clothing and collection trolleys are available at all times;
- Ensure that hospital attendants and ancillary staff immediately replace used bags and containers with the correct new bag or container as appropriate;

- Directly supervise hospital attendants and ancillary workers assigned to collect and transport healthcare waste.
134. Concerning waste storage, the WMO should:
- Ensure the correct use of the central storage facility for healthcare waste at the healthcare establishment, which shall be fenced with a lock on the entrance; hospital attendants and ancillary staff should always have immediate access to the storage area;
 - Prevent unsupervised dumps of waste containers on the hospital grounds, even for short periods of time;
135. To supervise evacuation or disposal of the waste, the WMO should:
- Co-ordinate and monitor all waste disposal operations;
 - Monitor methods of transportation of wastes on-site and off-site and ensure that wastes collected from the hospital are transported by an appropriate vehicle to the designated incinerator;
 - Ensure that waste is not stored on the hospital grounds for periods longer than specified in the guidelines and that the required frequency of collection is maintained; he or she should therefore liaise with the transport organisation, which may be the local authority or a private contractor.
136. For staff training and information the WMO should:
- Liaise with the matron and the hospital supervisor to ensure that the nursing staff and medical assistants are familiar with their responsibilities for segregation and storage of waste and of the limited responsibilities of hospital attendants and ancillary staff in the handling and transport of sealed waste bags and containers;
 - Liaise with departments heads to ensure that all doctors and other qualified clinical staff are aware of their responsibilities regarding segregation and storage of waste and of the limited responsibilities of hospital attendants and ancillary staff in the handling and transport of sealed bags and containers;
 - Ensure that hospital attendants and ancillary staff are not involved in waste segregation and that they only handle waste bags and containers sealed in the correct manner.
137. For incident management and control the WMO should:
- Ensure that emergency procedures are available and in place at all times and that personnel are aware of the appropriate action to be taken;

- Investigate or review incidents reported during the handling of healthcare waste.

7.7.2 Emergency Response

138. For healthcare establishments, spills of infectious or other hazardous material or waste are probably the most common emergencies related to hazardous material. Basically, the same response procedures are applied, regardless whether the spills are from material or waste. The response to emergencies should ensure the following:

- The waste management plan should be respected;
- Contaminated areas should be cleared and if necessary disinfected;
- The exposure of workers should be limited as much as possible during the operation;
- The impact on the environment should be limited to the extent possible.

139. The staff should be well prepared for emergency response, and the required equipment should be easily available at all points in time and within reasonable distance to ensure that adequate response can be carried out safely and routinely. The procedures for the different types of emergencies should be written up. For dangerous spills, clean up should be carried out by designated, specifically trained personnel.

7.7.2.1 Response to injuries

140. A programme of response should be established for immediate reaction to injuries or exposure to a hazardous substance. All staff handling biomedical and healthcare waste should be trained in dealing with injuries. Such a programme should include the following elements:

- Immediate first aid measures, such as cleansing of wounds and skin, and splashing of eyes;
- Immediate reporting to a responsible designated person;
- Retention, if possible, to the item and details of its source for identification of possible infection;
- Additional medical care, from an accident, emergency or occupational health department, as soon as possible;
- Medical surveillance;

- Blood or other tests if indicated;
- Recording the incident;
- Investigation, determination and implementation of remedial action.

7.7.2.2 Dealing with spills

141. Spills usually require only clean up of the contaminated area. In spills of infectious agents it is important to determine the type of infectious agent, as some may require immediate evacuation of the area, whereas others require fewer precautions. The more hazardous spills usually occur in laboratories rather than in healthcare departments.

Box 2: Example of general procedure for spill cleaning given by WHO

1. Evacuate the contaminated area
2. Eye and skin decontamination (disinfection) of exposed personnel should take place immediately
3. Inform the designated person (usually the waste management officer)
4. Determine the nature of the spill
5. Evacuate all the people not involved in cleaning-up if particularly hazardous agent
6. Provide first aid and medical care to injured persons (see response to injuries)
7. Secure the area to prevent additional exposure of persons
8. Provide adequate clothing to personnel involved in cleaning-up
9. Limit the spread of the spill
10. Neutralise or disinfect the spill or contaminated material if indicated
11. Collect the spill and the contaminated material
Sharps should never be picked up by hand, but with tools, e.g. pans or brushes. Spilled material and contaminated items used for cleaning should be placed into the appropriate bags or containers
12. Decontaminate or disinfect the area, and absorb
13. Rinse the area, and absorb
14. Decontaminate or disinfect the used tools
15. Take off protective clothing and decontaminate or disinfect it if necessary
16. Seek medical care if exposure to hazardous material has occurred during the operation

142. Spill cleaning procedures should specify safe handling operations and appropriate protective clothing. An example of such a procedure is provided in box 2. Appropriate equipment for collecting the waste, placing it in new containers, and for disinfection should be provided. Table 6 provides an example of required items.

Table 6: Example of a list of items for spillage cleaning given by WHO

| Action | Tools or items |
|----------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Approaching the spillage | Protective equipment |
| Containing the spillage | Absorbent material (e.g. absorbent paper, towels, gauze pads) |
| Neutralising or disinfecting the spillage (if necessary) | For infectious material: disinfectant* |
| | For acids: sodium or calcium carbonate or other base |
| | For cytotoxic material: special chemical degradation substances |
| | For bases: citric acid powder or other acid |
| Collecting the spillage | For liquids: absorbent paper, gauze pads, wood shavings, calcium bentonite, diatomaceous earth |
| | For solids: forceps, broom, dust pan or shovel |
| Containment for disposal | Mercury: Mercury sponge or vacuum pump |
| | Plastic bag (red, yellow or brown, as appropriate), sharps container |
| Decontamination or disinfection of the area | For infectious material: disinfectants* |
| | For hazardous chemicals: suitable solvent or water |

* Such as bleaching powder, which is a mixture of calcium hydroxide, calcium chloride, chloride and sodium hypochlorite used in powder form or in solution of varying dilution's (1:1 to 1:100) depending on the nature of the spilled material.

7.7.2.3 Reporting accidents and incidents

143. All waste management staff should be trained in emergency response and made aware of the correct procedure for prompt reporting of accidents and incidents. Accidents or incident, including near-misses, spillages, damaged containers, inappropriate segregation or any incidents involving sharps should be reported by the waste management officer if waste is involved, or otherwise to another designated person. The report should include:

- The nature of the accidents or incidents;
- Where and when it occurred;
- Which staff were directly involved;
- Other relevant circumstances.

144. The incidents should be investigated by the responsible officer (waste management officer in case of waste) to establish its causes and if possible take action to prevent recurrence. The records should be kept.

8 Waste management auditing

145. The purpose of a waste audit is to help a hospital determine which initiatives will be most beneficial. It does this by developing a detailed picture of the current status of waste generation and disposal for the hospital. It then identifies potential areas for improvement and develops action plans for each area. The ultimate impact of environmental action is judged in terms of positive impact on the environment and cost savings for the institution.

146. There are three major steps involved in the waste audit. They include information gathering, waste stream analysis and the development of action plans. First, a waste audit must collect information about

- the total volume of each type of waste generated by the entire hospital;
- the volume of each type of waste generated by each specific area in the hospital;
- the current costs associated with the disposal of each type of waste; and
- the waste management initiatives currently in place. Typically, these include reuse, reduction, recycling and recovery programs.

147. Much of the information can be found in purchase records and requisitions, estimates done by the facility, a search of the literature, and from interviews with staff and their experience in handling waste in the facility.

148. The next step in the waste audit is to proceed with the sorting and weighing of components of the waste stream or to conduct a waste stream analysis. This second task will be referred to as the comprehensive study of general waste. This task is usually accomplished by personnel from the housekeeping staff over a period of two weeks. For safety reasons, no types of waste that could threaten the staff in any way are sorted, that is, biomedical waste, sharps, chemicals and so on are weighed only.

149. The third stage of a waste audit is to develop action plans for re-use, reduction, recycling and recovery initiatives. This involves analysing the data collected and, in the first part of the audit, identifying potential areas of opportunity. Each of these areas is then investigated to identify potential benefits associated with realistic initiatives.

150. For each area where benefits can be achieved, an action plan is developed to implement the initiative. The plan identifies where existing systems and work habits can be modified, and where new systems could be introduced to achieve the desired results. While the action plan covers the entire hospital, the recom-

recommendations for action may focus on specific areas within the hospital where the most benefit can be gained.

151. Hospital managers or personnel making decisions need specific information about which types of waste are being generated, the volumes of these wastes and the locations of their generation. This information allows initiatives to be targeted to the specific hospital locations and/or types of waste for which the most significant benefits can be obtained. For example, waste recycling is most effective when the segregation of recyclables from nonrecyclables occurs at the point where the waste is generated. By the time a waste has reached the disposal hopper or compactor, it is too late to consider waste reduction, reuse or recycle options. Knowing the specific locations where most of the recyclable waste is generated permits the assessment of the recycling opportunity and the development of appropriate plans.

9 Capacity building

152. The objectives of a comprehensive capacity-building strategy could include the following:

- to provide a basic legal, technical and logistical framework,
- to introduce options for the sound management of biomedical and healthcare wastes,
- to develop a logical framework for the completion of biomedical and healthcare waste national profiles and the preparation of healthcare waste national plans

153. Elements of a comprehensive capacity building programme are:

- set up of a national committee for the environmentally sound management of biomedical and healthcare wastes;
- completion of national (local) healthcare waste profiles
- development of a national (local) healthcare waste management programme, including technical and financial plan
- preparation of national regulation on the environmentally sound management of biomedical and healthcare wastes
- undertake training programmes (healthcare personnel, wastes disposers, enforcement institutions, etc., including development of decision supportive tools for policy makers and waste handlers)

9.1 Education and training of personnel of healthcare establishments

154. A biomedical and healthcare waste management policy is not effective unless daily applied by all involved staff, in a consistent and accurate way. Training employees in implementing the policy is a critical step for a successful biomedical and healthcare waste management programme. The overall aim of the training is to develop awareness in the participants for health, safety and environmental protection issues relating to biomedical and healthcare waste, and how these can affect them in their daily work. It should highlight the employees' responsibilities and role in the overall management programme. Health and safety at the workplace and environmental awareness are everyone's responsibility.

155. All hospital personnel, including senior medical doctors, should be educated in order to convince them of the soundness of the comprehensive healthcare waste management policy of the hospital, and of its value for everyone's health and safety; this is the best way to obtain their collaboration for the implementation of this policy.

156. Training activities should be designed for and targeted to four main categories of personnel:

- Managers and regulatory staff, e.g. safety advisers;
- Medical doctors;
- Nurses and assistant nurses;
- Hospital cleaners, waste handlers and drivers.

157. Medical doctors may be educated through high-level workshops chaired by the head of the hospital and general hospital staff may be educated through formal seminars. The training of waste managers and/or regulators does not usually take place in the hospitals but in public health schools or hospital engineering university departments.

158. Education programmes should include;

- Information on each aspect of the healthcare waste policy and its justification;
- Informing each hospital staff member of his or her responsibilities and role in implementing this policy;
- Technical instructions on the application of the practices relevant for the target group.

159. As the best way of learning is probably through practice, hands-on training in small groups should be considered where relevant. Testing the participants at the end of the course, by simple true/false or multiple choice questions, often provides an incentive for learning, and gives a picture to the course organisers on the actual knowledge acquired by the participants. The more detailed course contents are exposed hereafter.

160. The instructors should have experience in teaching and training, be familiar with the hazards and practices of biomedical and healthcare waste management, and ideally have experience in waste handling.

161. Periodical repetition of courses will refresh the acquired knowledge, provide orientation for new employees and for existing employees with new responsibilities, and continuously update with policy changes. Follow-up training will provide data about the retention of information, and the need for refresher courses.

9.1.1 Training responsibility

162. The head of the healthcare establishment shall appoint a responsible person such as the infection control officer (ICO), the doctor for hygiene or the waste management officer for all training related to segregation, collection, storage and disposal of healthcare waste. He shall ensure that staff at all levels are aware of the hospital waste management plan and policy, and of their responsibilities and obligations within this plan and policy. A record of all training sessions should be kept. The content of training programmes shall be periodically reviewed and updated where necessary. For smaller sources of biomedical and healthcare waste, a central training function could be established at the regional health authority.

9.1.2 The training package

163. A training package could be developed by the national government agency responsible for the disposal of biomedical and healthcare wastes. Training packages are also being developed by the WHO, international agencies or development agencies.

164. The training package on biomedical and healthcare waste should be suitable for various types of healthcare establishments, including government hospitals, teaching hospitals, dental hospitals, polyclinics, health centres, healthcare research institutions, clinical laboratories and other establishments where healthcare wastes are generated. Such a training package would also be useful

for educational establishments and the sectors providing services for biomedical and healthcare waste disposal. The package should contain numerous illustrations, such as drawings, figures, photographs, slides or overhead transparencies.

9.1.3 Selection of participants

165. The ideal number of participants for a training course is 20 to 30 because greater groups may render discussions and exercises difficult. Training courses should be organised and targeted for all personnel categories. The discussions may however be easier if the group is composed by various disciplines (e.g. supervisors, medical and nursing staff, laboratory staff, engineers, ancillary staff), or if the group is laced with one or two medical assistants and nurses.

166. It may be beneficial to include senior administration staff and heads of department in certain training groups to show their commitment to the policy to other staff members, and to show that the policy is the responsibility of all personnel of healthcare establishments. Line managers may find it worthwhile to run the training sessions themselves, with their own personnel attending.

9.1.4 Training recommendations

9.1.4.1 Training recommendations for personnel providing healthcare

167. As mentioned above, the content of the training course should provide an overview of the waste management policy, its inherent rationale, and inform on relevant practices for the targeted group. E.g. personnel providing healthcare will mainly be informed about waste segregation practices:

- Care should be taken while removing needles from syringes during operations which require this;
- In no case should the staff correct segregation mistakes by removing items from a bag or container once disposed, or by placing a bag into a bag of another colour;
- Hazardous and general waste should not be mixed, however, where it has occurred, the mixture should be treated as healthcare risk waste;
- Nursing and clinical staff should ensure that adequate numbers of bag holders and healthcare waste containers are provided for the collected and on-site storage of medical waste in the wards, clinics, operating theatres

and other sources of waste generation. These on-site receptacles should be located close to the source of waste generation.

Upon completion of the training course, the staff should be aware of its responsibilities.

9.1.4.2 Training recommendations for waste handling staff

168. Relevant training chapters may constitute a basis for the training course. Addressed topics may include the waste management policy, health hazards, on-site transportation, storage, safety practices and emergency response. The attention of staff that routinely handling biomedical and healthcare waste may decrease with time, which will increase the risk of injury. Periodic training is therefore recommended.

9.1.4.3 Training of healthcare waste management operators

169. The minimal training requirements for waste management operators should include the following:

- Information on the risks associated with biomedical and healthcare waste handling;
- Training on the procedures for dealing with spillages and accidents;
- Instructions on the use of protective clothing.

The training needs will depend on the type of operations the staff performs. Depending on the duties, training on specific areas (e.g. operation of incinerators, waste transportation) will be required.

9.1.4.4 Training for staff transporting waste

170. The healthcare establishment may either transport the waste itself or contract an "authorised" waste transporter. Drivers and waste handlers should be specifically trained and be aware of the nature and risks of the transported waste. In particular, transport staff should be trained in the following issues, and be able to carry out the procedure and respect the instructions without any help from others:

- Correct procedures for handling, loading and unloading waste bags and containers;

- Procedures for dealing with spillages or accidents; for these procedures, written instructions should be available on the vehicle;
- Protective clothing and footwear should be worn at all times;

171. The dedicated vehicles for waste collection should carry at all times a supply of plastic bags, protective clothing, cleaning tools and disinfectants to cleanse and disinfect any spillage which may occur during loading, transport or unloading;

172. Documentation and recording of healthcare waste, e.g. by using a consignment note system, to allow waste to be traced from the point of collection to the final disposal facility.

173. The head of the healthcare establishment should liaise with the transport contractor to ensure that the waste collection crew is well trained. Untrained personnel should never be allowed to handle biomedical and hazardous healthcare waste.

9.1.4.5 Training of incinerator operators

174. Operation of incinerators requires qualified incinerator operators. It is reminded that the availability of such operators in certain regions should be checked before purchasing high-technology incinerators. If qualified operators are not available, healthcare establishments should either revert to alternative healthcare waste disinfection technologies, or contract the incineration through a regional facility.

175. Incinerator operators should have received at least secondary technical education. They should be specifically trained on the following subjects:

- Global functioning of the incineration facility, including heat recovery and flue-gas cleaning technologies, if existing;
- Health, safety and environmental implications of their operations;
- Technical procedures for operation of the plant;
- Emergency response, e.g. in case of equipment failures, alarms;
- Maintenance of the plant;
- Surveillance of ash quality and emissions according to the specifications.

9.1.4.6 Training of landfill operators of specially engineered landfill sites

176. The training of landfill operators is important for limiting subsequent risks of buried biomedical and healthcare waste, both in relation to prevent scavenging and to protect the quality of water. Operators should be trained in the following issues:

- Information on the health risks related to biomedical and hazardous healthcare waste;
- Instruction on the hazards related to sorting of this type of waste, which should in no case be practised by the landfill operators or other people;
- Handling of biomedical and healthcare waste by drivers or site operators should be limited to a minimum;
- Use of protective equipment and personal hygiene;
- Application of safe procedures to dispose the wastes on a landfill;
- Procedures for emergency response.

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Glossary/terminology

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| Activity | Disintegration of an amount of a radionuclide in a particular energy state at a given time per time interval at a given time |
| Air Pollution | The presence of a material or substance in air which may be harmful to either the natural or human environment, which includes any material present in sufficient concentrations for a sufficient time, and under certain circumstances to interfere significantly with the comfort, health or welfare of persons, or with the full use and enjoyment of property. |
| Air Quality Standards | The level of pollutants by law that cannot be exceeded during a specified time in a defined area. |
| Biomedical and Healthcare Waste | Solid or liquid waste arising from healthcare (medical) activities such as diagnosis, monitoring, treatment, prevention of disease or alleviation of handicap in humans or animals, including related research, performed under the supervision of a medical practitioner or veterinary surgeon or another person authorised by virtue of their professional qualifications. |
| Bottom Ash | The non-airborne combustion residue from burning fuel and other materials in an incinerator. The material falls to the bottom of the incinerator and is removed mechanically. |
| Capacity | The Quantity of solid waste that can be processed in a given time under certain specified conditions, usually expressed in terms of mass per 24 hours. |
| Chemical Waste | Wastes generated from the use of chemicals in medical, veterinary and laboratory procedures, during sterilisation processes and research. |
| Collection | The act of removing accumulated containerised solid waste from the generating source. Private collection of solid and liquid waste by individuals or companies from residential, commercial, health facility or industrial premises; the arrangements for the service are made directly between the owner or occupier of the premises and the collector. |

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| Cytotoxic Waste | Material which is visible contaminated with a cytotoxic drug during the preparation, transport or administration of cytotoxic therapy. |
| Decontamination | The process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances |
| Disinfection | The destruction of pathogenic micro-organism leading to a 10^{-5} reduction in microbial concentration. |
| Emergency | A situation created by an accidental release or spill of hazardous chemicals or infectious material which poses a threat to the safety of workers, residents, environment or property. |
| Exposure | The amount of radiation or pollutant present in a particular environment (i.e. human, natural) which represents a potential health threat to the living organisms in that environment. |
| Fly Ash | The finely-divided particles of ash entrained in the flue gases arising from combustion. The particles of ash may contain incompletely burned material. The particles are frequently glassy spheres but may also be crystalline or even fibrous in structure. |
| Healthcare Waste | See biomedical and healthcare waste |
| Human Tissue | The tissue, organs, limbs, blood, and other body fluids that are removed during surgery and autopsy. |
| Incineration | The controlled burning of solid, liquid or gaseous combustible wastes to produce gases and residues containing little or no combustible material. |
| Irradiation | Exposure to radiation of wavelengths shorter than those of visible light (gamma, x-ray, or ultraviolet), for medical purposes, the destruction of bacteria in milk or other foodstuffs, or initiation of polymerisation of monomers or vulcanisation of rubber. |
| Liquid Wastes | Any waste material that is determined to contain "free liquids" - liquids which readily separate from the solid portion of waste under ambient temperature and pressure. |

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| Monitoring | Periodic or continuous surveillance or testing to determine the level of compliance with statutory requirements and/or pollutant levels in various media or in humans, animals, and other living things. |
| Off-site Facility | A clinical and related waste treatment, storage or disposal facility that is located away from the generating site. |
| On-site Facility | A clinical and related waste treatment, storage or disposal facility that is located on the generating site. |
| Pharmaceutical Waste | Wastes from the production, preparation and use of pharmaceutical products. |
| Pyrolysis | The decomposition of organic material by heat in the absence of or with a limited supply of oxygen |
| Radioactive Waste | Material contaminated with a radio-isotope which arises from the medical or research use of radionuclides. It is produced, for example, during nuclear medicine, radio immunoassay and bacteriological procedures, and may be in a solid, liquid or gaseous form. |
| Residual Wastes | Those materials (solid or liquid) which still require disposal after the completion of a treatment or resource recovery activity, e.g., slag and liquid effluents following a pyrolysis operation, plus the discards from front-end separation systems. |
| Sanitation | The control of all the factors in the physical environment that exercise or can exercise a deleterious effect on human physical development, health, and survival. |
| Sharps | Objects or devices having sharp points or protuberances or cutting edges capable of cutting or piercing the skin. |
| Sterilisation | This is a process that kills all micro-organisms, including bacteria, viruses, spores and fungi. |
| Waste Minimisation | The application of activities such as waste reduction, re-use and recycling to minimise the amount of waste that requires disposal. |

Waste segregation The process of keeping source separated wastes apart during handling, accumulation (interim storage), storage and transport and to assist resource recovery and ensure appropriate designated treatment and/or disposal methods are utilised. Waste segregation should be practised by both generators and waste handling companies for efficient waste management.

Examples of Specific Waste Reduction, Reuse and Recycling Activities

Purchasing Practices

- Purchase recycled content material where appropriate (e.g. office paper, envelopes, toilet tissue, paper towels) and look for Environmental Labels. Work with purchasing committees to determine which products may be suitable.
- Work with suppliers to have oversized packaging materials returned or recycled.
- Use building construction products with recycled content materials (e.g. drywall, asphalt).
- Use environmentally responsible vehicles and maintenance products (e.g. propane as fuels, re-refined oils, retreated tires, recycled antifreeze).

Reduction

- Use two-sided photocopying.
- Use electronic mail (i.e. personal computers or phone messages).
- Buy in bulk (e.g. food and drink containers in the cafeteria and soaps and detergents in housekeeping).
- Avoid products with excess packaging and work with suppliers to reduce it.
- Reroute publications such as magazines, newspapers and journals.
- Circulate memos or documents.
- Use bulletin boards for posting announcements.
- Single space texts.
- Use two-way envelopes for billing.
- Make sure staff understand how to use equipment to reduce wastage.
- Use the reduction feature on your copier to fit more than one paper per page.
- Use permanent tape dispensers, not disposable ones.
- Use refillable pens instead of disposable ones.
- Purchase durable equipment, furnishings and supplies.
- Install energy efficient appliances (e.g. lighting).
- Use water-saving devices.
- Turn off lights and office equipment when not in use.
- Use incinerators that meet the new discharge guidelines and have an energy recovery system.
- Use computer fax software to send facsimiles without making hard copies.
- Use nonsolvent liquid scintillation cocktails in laboratories.

- Use less hazardous radioactive materials where appropriate.
- Develop microtesting procedures to reduce chemical usage.
- Make sure biomedical waste is properly segregated from general waste to reduce disposal costs and increase materials for recycling.
- Explore opportunities to reduce formalin usage in sample analysis by replacing with cold, physiological saline solutions where appropriate.
- Substitute formalin solutions with commercially available, less toxic cleaning solutions in dialysis machines.

Recycle

- Newspapers and telephone books can be given to farmers or humane societies as bedding.
- Recycle used towels and rags to rag recyclers.
- Use plain paper fax machines; these are recyclable and the messages will not fade.
- Recycle the following items in "blue box" programs, where available:
 - glass bottles from juice bottles or baby formula,
 - juice and food material containers,
 - newspapers and
 - plastic containers (e.g. pop containers or other types where appropriate).
- Recycle cardboard with commercial recycler or through your supplier.
- Recycle pallets with commercial recycler or through your supplier.
- Include pickup of containers as part of the supplier's role in your contracts.
- Work with suppliers to help them design workable packages that are recyclable.
- Send unwanted old equipment, furniture or medical supplies overseas.
- Pool local business together who recycle material and contract for the services of the same recycler to reduce pickup costs.
- When purchasing products, ensure that all packages can be returned to supplier or recycled at your facility.
- Use a distribution network to recycle materials back to a central location for better material marketing.
- Explore waste recycling options for food waste either as
 - human food
 - animal feed either directly or through a commercial processor and as
 - composting or vermiculture and use compost at your facility in landscaping.
- Contract a shredding company that recycles your shredded paper.
- Involve ambulatory patients in waste minimisation programs (e.g. psychiatric and geriatric patients in composting projects).

- For large waste generators, explore processing equipment such as balers or compactors for recyclable materials.
- Locate markets for recyclable materials which are generated in sufficient quantities, such as
 - office paper,
 - cardboard,
 - plastics,
 - solvents (xylenes, toluenes, CFCs),
 - oils (vegetable and hydraulic) and
 - construction and demolition materials such as drywalls, asphalt, concrete, wood.
- Install silver recovery units for photo processing wastewaters.
- Evaluate opportunities for anesthetic gas recycling.

Reuse

- Donate used publications to doctors' offices, nursing homes or the local library.
- Reuse worn cloth diapers and towels as rags.
- Reuse scrap paper for notepads and draft copies.
- Reuse old envelopes by applying labels (with nonsolvent glues) on top of old addresses.
- Use reusable diapers, incontinence and underpads where appropriate.
- Use reusable urine trays.
- Use reusable drapes and gowns where appropriate.

Annex IV**Validation of Waste Disinfecting Processes (April 1993)**

Directive Issued by the Bundesgesundheitsamt (German Federal Health Office) and the Deutsche Gesellschaft für Krankenhaushygiene (German Society for Hospital Hygiene)*

1 Application

This Directive relates to the validation of processes to disinfect waste belonging to the so-called C category, for which according to Section 10a of the German Epidemics Control Act disinfection is mandatory.

The "Instructions concerning the Avoidance and Disposal of Waste Generated by Public and Private Health Service Institutions" published by the Federal States Working Group on Waste (LAGA) in a special issue of the Bundesgesundheitsblatt (Federal Health Gazette 1992; 35: 30 - 38) contain the following comment:

Waste belonging to this category may conceivably originate in isolation wards, pathology departments, blood banks, surgeries, and veterinary practices or clinics as well as elsewhere. This category comprises waste material produced in consequence of the treatment of patients suffering from certain infectious diseases, which is contaminated by pathogen-bearing secretions or excretions; packaging material does not normally belong to this category. It does include, however, microbiological cultures prepared by University Departments of hygiene, microbiology, or virology, medical laboratories, and surgeries working in the fields described above.

What action is to be undertaken in each instance should be decided in consultation with the hospital epidemiologist in charge, making due allowance for local conditions.

For special types of waste not covered by Sections 4.3 to 4.4 as well as for specialised processes and containers, dedicated test conditions will have to be developed which reflect the peculiarities of the process and/or the type of waste concerned.

2 General Requirements

Only thermal processes are suitable for the disinfection of waste conforming to the definition in Section 10a of the Federal Epidemics control Act (so-called category-C waste). Processes should be given preference in which the medium is saturated steam¹ and in which air is evacuated mechanically. Chemical waste disinfection processes are unsafe and cause unnecessary environmental pollution.

In judging disinfection processes, it should be remembered that one of the fundamental principles of epidemics control is that the spread of pathogens must be prevented and/or contamination restricted to the original contaminated objects. Consequently, the following requirements shall apply:

- Process parameters shall be maintained on all interior and exterior surfaces of the waste material, and, if necessary, everywhere inside the waste material (in the case of so-called wet waste, for instance). Process parameters shall be designed to cover grades A, B, and C (cf. the list of disinfectants and disinfection processes reviewed and approved by the Bundesgesundheitsamt and/or Section 5 of this Directive).

* Reprint of the German text with kind permission by Carl Heymanns Verlag KG, Köln, Bundesgesundheitsblatt 1993: 36 (4): 158 - 160. mhp-Verlag GmbH assumes full responsibility for the English translation.

¹ Currently, the scientific data available about waste disinfection processes not involving saturated steam are not adequate to permit the formulation of test standards.

- Before the process of disinfection begins, the waste material to be disinfected shall not be re-packed, sorted, or pre-treated in any other way. Shredding² as well as the opening of containers before disinfection is admissible, provided that this is done within a closed system and that said system is disinfected immediately after the process of shredding and/or opening in accordance with the provisions of this Directive, and that any spread of pathogens is precluded.
- Hermetically sealed containers may only be intermingled with the product if they contain either water or some aqueous solution.
- Equalisation and cooling times shall be adjusted in relation to the nature of the waste material being treated, paying particular attention to the proportion of compact components and liquids. As a general rule, exposure periods shall be calculated so as to allow for isolated quantities of liquid amounting to 500 ml. The maximum quantity of liquid in each container shall be determined experimentally in the course of homologation testing.
- The packaging of the waste material shall be designed to accommodate the disinfection process. Waste material containers shall be designed to permit the passage of air and steam during the process of disinfection or, alternatively, to open or destruct automatically during the phase of air evacuation to ensure proper disinfection afterwards.
- There shall be no hazard of pathogens or infections being spread by the disinfection system either in operation or during maintenance and repair. Depending on the process involved, it may be necessary to install suitable systems for treating the exhaust air and waste water.
- At the end of the disinfection and/or operating cycle³ not only shall the product itself be disinfected but also each and every part of the apparatus that has been in contact with the contaminated product. The same shall be assured in the event of malfunction.

² In the context of processes involving shredding, the requirements of this Directive shall be applied *mutatis mutandis*; in particular, disinfection shall take place under saturated-steam conditions; i.e. with both temperature and pressure conforming to the saturated-steam curve.

The following points should be observed:

With regard to Section 4.1 and 6.1

Pressure as well as temperatures at critical locations within the product shall be monitored. Temperature fluctuations within the product and the pressure curve over time shall be measured and recorded. Sanitisers shall be equipped with outlet nozzles for the purpose.

With regard to Section 4.3

Depending on the intensity of the shredding process, the hosepipe in the test carrier may be shortened. Test carrier shall be added to the product after shredding.

With regard to Section 7.1

The intensity of shredding shall be determined during homologation.

Shredders shall be designed to ensure that access for repair and other purposes is possible only after the completion of the disinfection cycle. For this reason, the homologation test shall include an investigation of a shredder malfunction in the form of a disinfection test of the input section inclusive of the shredder. In this test, lumens conforming to DIN 58948, Part 13, shall be used together with biological indicators conforming to DIN 58949, Part 4, Item 6. The test carrier shall be packaged without extra padding on a vapour-permeable wrapper such as, for instance, a transparent sterilisation package conforming to DIN 58953, Part 4 and deposited in front of the deactivated shredder. Furthermore, a disinfection process shall be defined in the course of the homologation test which may be used at the end of each operating cycle to disinfect all parts of the apparatus that might have been contaminated. As a rule, it will be perfectly adequate to document such disinfection by conducting measurements of the physical process parameters in certain critical locations within the system. In cases of doubt, biological indicators conforming to DIN 58949, Part 4, Item 6 may be placed, for instance, in receptacles, i.e. tubeless test carriers, conforming to DIN 58948, Part 13.

With regard to Section 7.3

Routine tests shall comprise a review of the disinfection process used to disinfect the system at the end of each operating cycle with the aid of physical parameter measurements.

³ In non-stationary systems, the end of an operating cycle may be equivalent to the changeover to another source of waste. To cover this contingency as well as any malfunctions, an automatic disinfection cycle shall be provided.

3 Test Versions

3.1 Homologation Tests

The purpose of homologation is to determine what operating data are to be used in the operation of a specific type of disinfection apparatus. At the same time, it serves to determine exactly what products may be disinfected by the process in question, what loading and/or packaging regulations should be followed, and where critical levels for measurements to be carried out in the future lie. Another purpose of homologation testing is to check conformance with general requirements (see Section 2 of this Directive) particularly with regard to malfunctions and the innocuousness of waste water and exhaust air. Homologation tests shall be performed exclusively on application by the manufacturers. Only after the completion of such a test can an application be made for inclusion in the Bundesgesundheitsamt list in accordance with Section 10c of the Federal Epidemics Control Act.

3.2 Commissioning Tests

The inspection and testing of sanitisers on site serves the purpose of demonstrating that a particular unit is capable of conforming to the relevant general requirements, provided there is no deviation from the operating instructions. The operating data determined in the course of homologation testing shall be applied to the operation of the unit on site, which necessitates proper loading and a proper supply of expendables. This test may be commissioned either by the manufacturers or the suppliers of the unit.

3.3 Periodic Performance Tests⁴

Periodic performance tests shall be conducted on site at intervals of no more than six months. their purpose is to demonstrate that the disinfection performance of the sanitiser is good and that it causes no infection hazard, provided there is no deviation from the operating instructions and a proper supply of expendables is at hand.

3.4 Unscheduled Tests

Unscheduled tests shall be conducted whenever there has been a change in the type, quantity, or packaging of the waste material being treated, whenever there is cause to suspect that the efficiency of the sanitiser has been impaired, or whenever repairs have been effected by which said efficiency might have been impaired.

4 Test loading

4.1 General

Test loads shall comprise a variety of material, the composition of which should reflect that of the waste material actually being treated. The test should provide for treating one full load of both porous and liquid products (see Section 4.1 and 4.4 of this Directive). In the test only those containers shall be used which will later on hold the contaminated product.

Measuring implements, i.e. thermoelements and biological indicators, shall be distributed at critical points throughout the product in a representative manner. To facilitate retrieving the biological indicators after the test their locations shall be marked. In processes in which containers are

⁴ Each sanitiser shall be equipped with a comprehensive set of control and monitoring instruments and equipment to ensure the safety of the process. Routing test intervals shall be laid down in the homologation test report. In this context, it is of importance to note that the information leaflet published by LAGA calls for inspecting waste disinfection systems at three-month intervals.

automatically destructed at the start of the air evacuation cycle the critical points are at the centre of the test batch. In containers fitted with apertures such as, for instance, vents or filters in the cover, the critical zone as a rule is somewhere near the bottom of the container.

The vents or filters of waste material containers shall be function-tested under conditions simulating use by, for instance, filling them with shallow dishes containing nutrient substances.

4.2 *Porous Products*

Containers shall be filled with horizontal layers of cellulose arranged as uniformly as possible, the objective being to avoid cavities. The biological indicators shall conform to DIN 58949, Part 4, Item 6.

4.3 *Lumens*

To simulate hollow objects that are open at one or two ends, test carriers that conform to DIN 58948, Part 13, shall be used together with biological indicators conforming to DIN 58949, Part 4, Item 6. Test carriers shall be packed in the requisite containers and placed in the disinfection chamber without any additional padding.

4.4 *Liquid Products*

Liquids shall be simulated by plastic bottles filled with 0.5 l of water. Thermoelements shall be inserted in the liquid to monitor its temperature. As an additional measure, biological indicators may be used which should be designed and placed to ensure that meaningful data about conformance with the process parameters can be obtained. Regulations covering these biological indicators are currently under preparation.

5 Biological Indicators

The biological indicators used shall conform to DIN 58949, Part 4, Item 6. This standard also covers the packaging, storage, and resistance testing of these bioindicators. As an additional measure, the homologation test at least shall involve a quantitative test for germs surviving on the biological indicators. This, in turn, necessitates a quantitative resistance test of these bioindicators by the standard process (saturated steam, 100 °C, 15 min). Germ count reductions shall be recorded.

This quantitative evaluation affords more insight into the safety margin of a process.

6 Physical Process Parameter Measurements⁵

6.1 *Temperature*

The thermoelements used shall be fitted with wires equipped with sturdy, heat-resistant insulation sheathing. Thermoelements shall be placed at all critical points within a test batch, one extra thermoelement being placed at the most unfavourable location within the disinfection chamber but outside the product proper. There shall be facilities for automatic test data recording. Temperature data shall be precise to within ± 1 K (calibration in accordance with DIN 58946, Part 3, Item 6.2.2).

It is recommended to use thermoelements equipped with sensors made of either copper/copper-nickel or nickel-chromium-nickel having a maximum diameter of 1 mm inclusive of insulation. The recorder used should be a temperature-compensated dotted-line recorder with a minimum of six input ports and

⁵ Whenever necessary, due allowance should be made for the results of CEN TC 102 (requirements as per pr EN 285).

a range of between 20 and 150°C (equivalent to 0 to 100 %), a usable width of 100 mm, a dot interval length of 1 s whenever possible (maximum 2.5 s), and a paper feed rate of 240 ,mm/h minimum.

6.2 *Pressure*

Pressure shall be measured by means of an absolute-pressure gauge with an indication or, is possible, recording imprecision of no more than ± 6 mbar. This pressure gauge shall be adequately protected by overtemperature and overpressure protection devices.

7 **Test Scope**

7.1 *Homologation Tests*

Biological indicators shall be exposed within the empty disinfection chamber. Temperature distribution shall be recorded and documented.

Processes shall be tested both under partial and under full load (cf. DIN 58949, Part 3) inclusive of all the loads specified in Section 4. In those processes where it appears fundamentally likely that difficulties might arise in treating batches mainly consisting of porous or liquid products, the test should include batches consisting exclusively of products as defined in Section 4.2 and/or Section 4.4. As a minimum, batches consisting of single containers completely filled with porous or liquid product shall be tested.

The test batches described in Sections 4.2 and 4.2 may be omitted in the testing or processes designed for liquids only.

Biological indicators shall be used to determine the limits or process efficiency. Containers filled with porous product shall be fitted with no less than 10 bio-indicators preferably placed in critical locations. The container, in turn, shall itself be placed in a critical location within the disinfection chamber. In "lumen" and "liquid" test batches, at least five of the test carriers used shall be equipped with biological indicators: in quantitative tests, three biological indicators suffice as a rule.

Tests shall be repeated no less than twice. Tests of processes not belonging to the fractional-vacuum category described in DIN 58949, Part 1, shall be repeated four times.

Homologation test records shall show what exposure time, i.e. the inactivation time plus a fixed safety margin, has been determined experimentally. Furthermore, such reports shall contain descriptions of critical locations and critical batches.

7.2 *Commissioning Tests*

As a minimum, one test involving a test batch of lumens shall be conducted. The test shall involve no less than five test carriers fitted with bio-indicators. The batch in the disinfection chamber shall be one of the critical batches, identified in the homologation test or, alternatively, a full load.

Furthermore, these tests shall involve measurements of all physical parameters. In processes designed for liquids only the test batch shall conform to Section 4.4.

7.3 *Periodic Performance Tests*

Tests involving biological indicators shall be conducted as described in Section 7.2. In addition, the physical parameters of a process should be measured once a year.

7.4 *Unscheduled Tests*

To be conducted as described in Section 7.2.

8 Test Records

As a minimum, test records shall show the following:

- The sanitiser's make, type designation, and factory number;
- The type of test conducted;
- A description of the procedure involved;
- The type and weight of the load together with a description of the containers used;
- The location of the biological indicators and thermoelements (if any) within the sanitiser;
- Process parameter measurements, if applicable (local curves and histograms);
- The results of the microbiological test inclusive of the biological indicator resistance test. Reports shall show the makes of biological indicators used as well as their batch numbers, expiration dates and, if necessary, package types.

Annex V

Table 7: Emission standards for waste incinerators (in mg/m³ at 11 % O₂ dry) set by the European Union

| Pollutant | EC Directive on the Incineration of Waste | | |
|-------------------------------------------------|------------------------------------------------------|----------------------------------------------------|---------------------------------------------------|
| | daily average limit | A - half hour average limit 100 % ²⁾ | B - half hour average limit 97 % ²⁾ |
| HCl | 10 | 60 | 10 |
| HF | 1 | 4 | 2 |
| SO ₂ | 50 | 200 | 50 |
| NO _x | 200 | 400 | 200 |
| CO | 50 | 100 | 50 |
| Organic substances | 10 | 20 | 10 |
| Dust | 10 | 30 | 10 |
| Heavy metals | average emission limit over respective sampling time | | |
| | [½ - 8 h] | | |
| Σ Cd and Tl | 0,05 | | |
| Hg | 0,05 | | |
| Σ As, Sb, Cr, V, Sn, Pb, Co, Ni, Cu, Mn | 0,5 | | |
| | [6 - 8 h] | | |
| Dioxins and furans (as toxic equivalent values) | 0,1 x 10 ⁻⁶ TE ¹⁾ | | |

1) = 0,1 ng TE/m³

2) either none of the half-hourly average values exceeds any of the emission limit values set out in column A or, where relevant. 97 % of the half-hourly average values over the year do not exceed any of the emission limit values set out in column B