

Safe management of healthcare waste: A public consultation

Gateway no 5471

Executive summary

Introduction

This consultation document has been produced as a best practice guide to the management of healthcare waste.

It is based on that previously provided by a document entitled 'Safe disposal of clinical waste' (1999) produced by the Health Services Advisory Committee and published by the Health and Safety Commission.

The guidance has been revised and updated to take into account the changes in legislation governing the management of waste, its storage, carriage, treatment and disposal, and health and safety.

Aim of this guidance

This guidance has been produced to provide a framework for good practice waste management to help NHS trusts and other producers to meet legislative requirements. The advice in this document and any recommended courses of action are not in themselves mandatory, but Trusts, or others, choosing not to follow them are advised that it is essential that equivalent steps are taken to comply with all relevant legislation.

Who should use this guidance

This guidance has been written for all those involved in the management of healthcare waste and provides practical advice and guidance for waste producers. Whilst the main body of this guidance focuses on healthcare waste management issues associated with NHS healthcare practice, its content is also aimed at all producers of healthcare waste.

Key recommendations

This guidance recommends adopting:

- A new methodology for identifying and classifying **infectious** and **medicinal** wastes that complies with health & safety, carriage and waste regulations. The new methodology is described as the 'unified' approach. Use of this approach is not mandatory but is considered best practice. Compliance with the unified approach will ensure that producers comply with and go beyond the regulatory requirements.

- A revised colour-coded best practice waste segregation and packaging system. Producers may wish to adopt this system to aid the identification and segregation of their waste. By adopting the best practice system, standardisation can be achieved across the UK.
- The use of European Waste Catalogue (EWC) codes. Unlike previous guidance documents, the use of the clinical waste classification system using Groups A to E has been removed as it is felt that its continued use is inappropriate. The A to E classification system no longer reflects appropriate segregation for treatment or disposal and does not easily equate to the use of European Waste Catalogue (EWC) Codes, which are now mandatory for all waste transfer documentation.
- An offensive waste stream to describe wastes which are non-infectious (human hygiene waste and sanpro waste such as nappies, incontinence pads etc).

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1.0 Introduction

The guidance provided in this document has been produced by Department of Health, Estates and Facilities Division, and approved by a project steering group whose members included representatives of NHS organisations, Department of Environment Food and Rural Affairs (DEFRA) and regulatory agencies from across the UK. In preparing this guidance additional advice and information has been provided by a broad cross section of the healthcare waste industry including producers, waste management and other contractors and manufacturers of equipment and supplies.

The guidance is based on that previously provided by a document entitled 'Safe Disposal of Clinical Waste' produced by the Health Services Advisory Committee and published by the Health and Safety Commission. This guidance has been revised and updated to take into account the numerous changes in the legislation governing the management of waste, its storage, carriage, treatment and disposal, and health and safety. Of particular relevance are:

- Waste Management Licensing Regulations 1994 (as amended);
- The Landfill (England and Wales) Regulations 2002;
- The Hazardous Waste (England and Wales) Regulations 2005,
- The List of Waste (England) Regulations 2005,
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2005 (the Carriage Regulations); and
- The Control of Substances Hazardous to Health Regulations 2002 as amended (COSHH).

1.1 Key Changes from Safe Disposal of Clinical Waste (1999)

Key changes contained in this document include guidance on:

- The definition and classification of infectious wastes in accordance with hazardous waste regulation and associated guidance published by the regulatory agencies;
- The definition and classification of medicinal wastes, including cytotoxic and cytostatic wastes, in accordance with hazardous waste regulation and associated guidance published by the regulatory agencies;
- Changes in carriage regulation brought in by the Carriage Regulations , as amended in 2005
- A revised colour-coded best practice waste segregation and packaging system;
- The use of European Waste Catalogue (EWC) Codes.

Unlike previous guidance documents the use of the clinical waste classification system using Groups A to E has been removed as it is felt that its continued use is inappropriate. The A to

E classification system no longer reflects appropriate segregation for treatment or disposal and does not easily equate to the use of European Waste Catalogue (EWC) Codes, which are now mandatory for all waste transfer documentation.

Section 5 of this document contains a classification system for healthcare waste which reflects and summarises the key requirements of waste, health & safety and carriage regulation. This approach, developed by the project working group, is described as the 'Unified Approach'. This single classification system complies with the principal regulatory requirements and contains additional elements of best practice.

1.2 Scope and Applicability

A wide variety of wastes are produced from healthcare activities. This guidance covers those wastes produced directly from healthcare activities and focuses on the management of medicinal and infectious wastes.

This guidance has been written for all those involved in the management of healthcare waste and provides practical advice and guidance for waste producers. Whilst the main body of this guidance focuses on healthcare waste management issues associated with NHS healthcare practice its content is also aimed at all producers of healthcare waste. The sector guides at the rear of this document have been specifically designed to meet the needs of a broad range of healthcare waste producers.

[Note that sector guides not ready for external consultation].

1.3 Who should use this Guidance

This guidance provides practical advice for all those involved in the management of healthcare waste and is applicable to all who manage or come into contact with healthcare waste.

1.4 Status of the Guidance

The guidance has been produced to provide a framework for good practice waste management in order to help NHS Trusts, and other producers, meet legislative requirements. The advice in this document and any recommended courses of action are not in themselves mandatory, but Trusts, or others, choosing not to follow them are advised that it is essential that equivalent steps are taken to comply with all relevant legislation. This guidance may be used by NHS Foundation Trusts for information. Health and Safety Inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

It is anticipated that this guidance will be used by all those involved in the waste management process including waste producers; waste contractors and regulators, providing a basis of common understanding for all parties.

References within this guidance relate to the minimum approved standard or technological solution and further information on treatment and disposal options should be sought from waste management contractors and the appropriate regulatory agency.

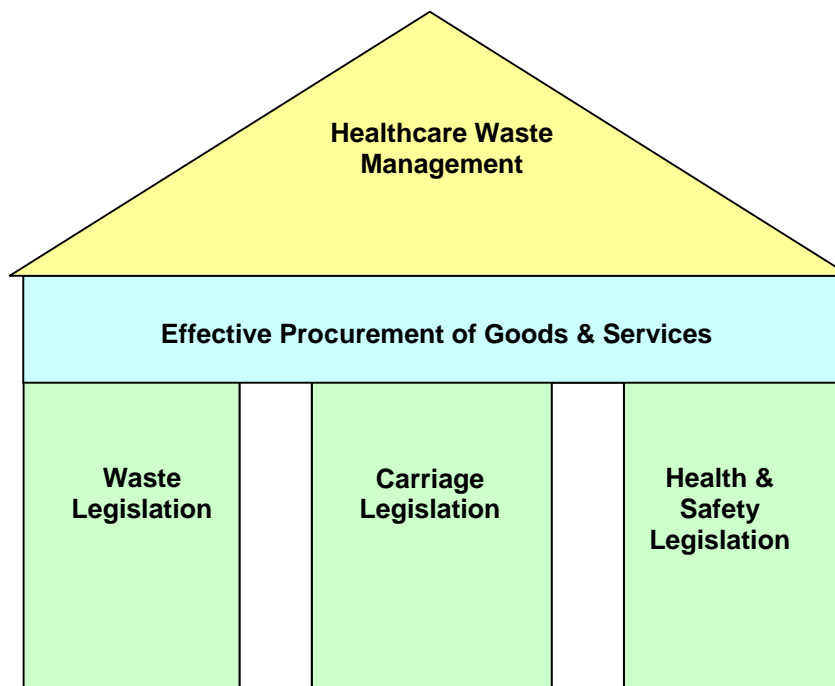
1.5 Devolved Regulation

The guidance provided in this document relates specifically to NHS premises in England and Wales, and references to legislation is to that applicable in England and Wales. The regulatory requirements for Scotland and Northern Ireland, as well as Wales are essentially similar but, gradually regulatory requirements are being subjected to regional variation as devolved government develops. It is essential that the applicability of particular legislation should be checked before decisions are finalised.

2.0 Introduction to Legislative Requirements

In order to effectively manage those wastes arising on healthcare premises, those responsible for the management of the waste must understand and comply with the requirements of three separate regulatory regimes: waste, transport and health & safety legislation. In order for waste management practices to comply with these requirements appropriate waste management services need to be procured.

The figure below shows the relationship between the three regulatory approaches and effective procurement of goods and services in relation to the management of healthcare waste.



2.1 Waste Legislation

Waste Regulation in the UK relies on a variety of licences and permits to control waste management activities. In addition to these all those involved in the management of waste, including producers have responsibilities, outlined by the Duty of Care, to ensure that waste is managed appropriately.

2.11 Waste Management Licenses and Permits

Permits or licences allow certain activities to be carried out in accordance with conditions specified by the regulating authorities. The Environment Agency (EA) is the regulatory authority responsible for waste management activities in England and Wales,

The Environmental Protection Act 1990 (EPA), Waste Management Licensing Regulations 1994 (as amended) and The Pollution Prevention and Control (PPC) Regulations 2000 provide a legislative system for the regulation waste management designed to ensure that waste is managed in a way which will prevent pollution or harm to human health.

In summary a PPC Permit, a waste management licence or an exemption from licensing is required for the storage, treatment and disposal of a wide variety of wastes. Generally, a licence is not required for the storage of waste on the site where it is produced, subject to the conditions of the relevant exemptions being met.

Guidance on waste management permits and licenses in relation to storage and treatment/disposal of waste can be found in Chapter 12.

2.12 Duty of Care

The statutory requirements covering duty of care in waste management are contained in Section 34 of the Environmental Protection (EPA) Act 1990 and the Environmental Protection (Duty of Care) Regulations 1991. Everyone involved in the management of waste, regardless of the need for a licence or a permit, has a duty of care to ensure that waste is managed appropriately. The Department of Food and Rural Affairs (DEFRA) have produced a guidance document titled '**Waste Management, The Duty of Care: A Code of Practice**' which can be downloaded from the DEFRA web site or ordered from the Stationery Office.

The statutory duty of care applies to everyone in the waste management chain. It requires producers and others who are involved in the management of the waste to prevent its escape and to take all reasonable measures to ensure that the waste is dealt with appropriately from the point of production to the point of disposal. A key element to the duty of care is the requirement for a written description, adequately describing the type and quantity of waste, to accompany the waste as it is moved from point of production to point of final disposal. (See Section 13.2 Transfer Notes).

2.13 Waste Specific Regulations

Other, waste specific, regulatory requirements apply to many healthcare wastes, including but not limited to:

- The Hazardous Waste (England and Wales) Regulations 2005 (see sections 2, 4, 5, 7.2, & 13.32);
- The List of Waste (England) Regulations 2005;
- Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended) (see sections 2.25, 11.53);
- The Animal By-Products Regulations 2003 (see section 13.4) ;
- Radioactive Substances Act 1993 (see sections 4.42, 11.56)

Many of the regulatory requirements place duties on the producers of waste to:

- Notify the regulatory agencies before the waste is produced or transferred;
- Specify the minimum pre-treatment and/or disposal requirements.

Whilst this guidance contains information about the above, further waste specific guidance should be sought from the following web sites:

- Department of Environment Food and Rural Affairs (DEFRA): www.defra.gov.uk
- Environment Agency (EA): www.environment-agency.gov.uk
- Health & Safety Executive (HSE): www.hse.gov.uk

2.2 Health and Safety Legislation

Health and Safety legislation is based on the assessment of risk. Schedule 3 of the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH 2002) and The Management of Health and Safety at Work Regulations 1999, pursuant to the Health and Safety at Work Act 1974, specifically require those dealing with potentially infectious materials, (including waste), to assess the risk to both their staff and the public who may come into contact with it. In practice, this involves the development of risk assessment policies and procedures and putting in place arrangements to manage the risks effectively. Arrangements for managing healthcare waste need to be part of an employer's overall health and safety management system. A number of guidance documents are available in relation to the management of infectious waste including:

- **The Management of Health and Safety in the Health Services**, produced by the Health Service Advisory Committee (HSAC);
- **Biological agents: managing the risks in laboratories and healthcare premises**, produced by the Advisory Committee on Dangerous Pathogens and published on the Health and Safety Executive (HSE) website;
- **Infection at Work: Controlling the Risks**, produced by the by the Advisory Committee on Dangerous Pathogens and published on Health and Safety Executive (HSE) website (This guidance is aimed at those working with infectious agents [often unintentionally] and not in laboratories or healthcare, e.g. schools.).

2.21 Management Responsibilities

Employers are responsible for complying with health and safety legislation. Even if staff are self employed for tax or national insurance purposes, they are treated as employees for health and safety purposes. If any doubt exists about who is responsible for the health and safety of a worker, this should be clarified and included in the terms of a contract. However, legal duties with respect to The Health and Safety at Work Act 1974 cannot be passed on by means of a contract.

2.22 The Control of Substances Hazardous to Health Regulations 2002 (as amended)

The COSHH Regulations provide a framework of actions designed to control the risk from a range of hazardous substances, including healthcare waste.

COSHH - Key Points

Employers must, amongst other things:

- assess the risks to employees and others from healthcare waste;
- make arrangements for reviewing the assessment as and when necessary, but at no less than 2 yearly intervals and sooner if there is any reason to suggest the risk assessment is no longer valid; ;
- aim to eliminate or prevent these risks, and if this is not possible to adequately control the risks;
- provide suitable and sufficient information, instruction and training for employees about the risks;
- provide health surveillance and immunisation, where appropriate.

2.23 The Management of Health and Safety at Work Regulations 1999

The Management Regulations and their associated Approved Code of Practice (ACOP) provide a framework for managing risks at work, including risks from healthcare waste, not covered by more specific requirements such as COSHH.

The Management Regulations - Key Points

Employers must amongst other things:

- make a suitable and sufficient assessment of the risks to employees and others. If they have 5 or more employees they must record the significant findings of the assessment;
- take particular account in their assessment of risks to new and expectant mothers and their unborn and breast feeding children;
- take particular account in their assessment of risks to young people;
- make arrangements for the effective planning, organisation, control,
- monitoring and review of any precautions;
- provide health surveillance where appropriate;
- have access to competent health and safety advice;
- provide information for employees;
- co-operate with other employers who may share the workplace.

2.24 Consulting Employees

The Health and Safety (Consultation with Employees) Regulations 1996 and The Safety Representatives and Safety Committees Regulations 1977 deal with consultation of employees directly and via recognised trade unions.

Employers must consult employees and their representatives about aspects of their health and safety at work, including:

- any change which may substantially affect their health and safety;
- the employer's arrangements for getting competent health and safety advice;
- the information provided on reducing and dealing with risks;
- the planning of health and safety training;
- the health and safety consequences of introducing new technology.

By incorporating health and safety requirements in healthcare waste policy employers are able to provide staff with information relevant to their job or role. The policy can then be used as a basis for training and discussions.

The Health and Safety Executive or Local Authorities (Environmental Health) are the regulatory bodies with responsibility for enforcing health and safety legislation. The division of enforcement responsibilities is determined by the Health & Safety (Enforcing Authority) Regulations 1998

2.25 The Genetically Modified Organisms (Contained Use) Regulations 2000.

The Genetically Modified Organisms (Contained Use) Regulations 2000 specify the containment and inactivation requirements for waste contaminated with Genetically Modified Organisms (GMOs) and Genetically Modified Micro-Organisms (GMMs). The Regulations definition of genetic modification activity is all encompassing and includes the transportation and the process of destruction or inactivation of waste. All those involved in genetic modification activities, including waste contractors, are required to be registered as GM Centres. Guidance on registration, packaging, transport and disposal of this waste stream is available from the HSE. The HSE publication 'A Guide to Genetically Modified Organisms (Contained Use) Regulations 2000 provide comprehensive information.

2.3 Carriage Regulation

Carriage Regulation is based on the principle of hazard assessment and materials (including waste) are classified according to their primary hazard. The carriage of dangerous goods (those materials with an identifiable hazard) are subject to regulatory control. The Carriage Regulations are intended to reduce, to reasonable levels, the risk of harm or damage to people, property and the environment posed by the carriage of dangerous goods.

Carriage Regulation – Key Points

The regulations cover (by reference to ADR) amongst other things:

- Training of personnel involved in the chain of distribution,
- Product classification and identification,
- Packaging,
- Documentation,
- Safety equipment and emergency procedures,
- Safe loading,
- Vehicle specification and operation

Duties are imposed on parties at all stages of the supply chain including manufacturers, consignors, carriers and receivers.

2.31 The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 4, as amended in 2005 (the “Carriage Regulations)

The Carriage Regulations implement in Great Britain the requirements of European and International Transport regulation produced by the United Nations (UN). The Carriage

Regulations make direct reference to the European Agreement ' *Accord Européen Rélatif Au Transport International Des Marchandises Dangereuses Par Route*, known as 'ADR'. ADR is revised bi-annually and the updated regulations are incorporated into the UK by revision to the Carriage Regulations. Other European and International regulations apply to the movement of dangerous goods by road, sea, rail and inland waterway. It is recommended that producers seek specialist advice if healthcare waste is to be transported by means other than road transport.

In the UK the vast majority of dangerous goods are carried by road. The Carriage Regulations were amended in 2005 to bring them in to line with ADR 2005, which in turn changed some of the definitions of infectious substances including health care and clinical waste. They regulate the movement of dangerous goods by road in Great Britain (with equivalent provisions in Northern Ireland). These regulations apply irrespective of ownership of the goods therefore an organisation carrying its own 'goods' is treated in the same way as a third party contractor. The regulations apply to carriage on any road to which the public has access which in effect means that all roads on hospitals sites fall within the scope of the regulations.

In addition to the requirements of the Carriage Regulations the consignment and carriage of radioactive material such as medical isotopes is regulated by the Radioactive Material (Road Transport) Regulations 2002.

The Health and Safety Executive, the Police and the Vehicle and Operator Services Agency (VOSA) are the regulatory bodies responsible for enforcing carriage regulation in the UK. Carriage of radioactive material is regulated by the Department of Transport.

2.32 Dangerous Goods Safety Advisor

The Carriage Regulations require those involved in the carriage of dangerous goods to appoint a qualified Dangerous Goods Safety Advisor (DGSA). Duty-holders can appoint a member of staff to be the DGSA or a 'consultant' DGSA may be used. There are certain exemptions where a DGSA is not required (see Carriage Regulations 12(3)). However, it is recommended that DGSA advice is sought in relation to activities which include the carriage, or related packaging, loading, filling, or unloading of dangerous goods. A DGSA will also be able to provide information and advice relating to any exemptions available which in turn may reduce the requirements to comply with the Carriage Regulations.

It is the duty of the DGSA to monitor and advise on dangerous goods carriage compliance and ensure relevant incidents/accidents are properly investigated and reported. They must also prepare for the duty-holder an annual report on dangerous goods activities. The number of DGSAs to be appointed is not prescribed, other than there should be a sufficient number appointed to ensure their functions and duties can be carried out effectively. The DGSA regulations apply to carriage by road, rail or inland water-way.

FUNCTIONS OF THE DGSA

The functions of the DGSA are as follows:

- monitoring compliance with the rules governing the transport of dangerous goods;
- advising the employer on the transport of dangerous goods;
- ensuring that an annual report to the employer is prepared on the activities of the employer concerning the transport of dangerous goods;
- monitoring practices and procedures relating to the activities of the employer which concern the transport of dangerous goods.

It is important that all those involved in the movement of healthcare waste are aware who provides DGSA support. The name and contact Number(s) of the DGSA(S) should be listed in the sites waste management policy.

Guidance on the Carriage Regulations and ADR is available from the HSE in a document titled ‘ **Working With ADR – An Introduction to The Carriage of Dangerous Goods by Road**’ Other information is also available on the HSE website “carriage of dangerous goods” pages

2.4 Procurement Regulations

2.41 European Procurement Regulations

In addition to the Waste, Transport and Health and Safety Regulations, Procurement Regulations must also be taken into consideration. All publicly funded organisations, including the NHS, must ensure that all contracts established to collect and treat waste conform to the European Union (EU) Public Procurement Regulations, notably The Supplies Directive 93/36/EC (as amended by 97/52/EC).

Waste disposal and collection services are classified by the EU as being a Service Category and are controlled by The Public Contracts (Works, Services and Supply) (Amendment) Regulations 2000. In accordance with these Regulations the NHS and other public sector organisations are required to publicly advertise all waste contracts, which exceed pre-set threshold limits set by the EU, in the Official Journal of the European Union (OJEU). The thresholds are revised every two years.

The aggregate value of contracts should be considered and not the annual value of the agreement. For example; if a healthcare waste contract is valued at £60,000 per annum it may on face value fall outside of the EU threshold to follow the EU procedures. However, if this contract is for a three year period, the aggregate value of the contract is £180,000, which

will exceed the OJEU threshold and therefore will be subject to the requirements of The Public Contracts (Works, Services and Supply) (Amendment) Regulations 2000.

Information about Public Procurement Regulations and OJEU thresholds can be obtained from the Department of Culture, Media and Sport: www.culture.gov.uk.

2.42 Procurement Guidance

Further information on the EU Public Procurement Regulations and how to develop and competitively tender waste collection and disposal contracts is available online from the NHS Purchasing and Supply Agency:

http://www.pasa.nhs.uk/sustainabledevelopment/waste/waste_procguide.stm

Information on revised EU Public Procurement Regulations/OJEU thresholds is also available on line from the NHS Purchasing and Supply Agency: <http://www.pasa.nhs.uk/purchasing/>

3.0 Healthcare Waste Policy

In order to effectively manage healthcare waste all those involved in the management of the waste stream should have access to an appropriate healthcare waste policy which clearly identifies who is responsible for the waste and how it should be managed. The policy should clearly identify the legal obligations set out in waste, health and safety and carriage legislation. The policy should provide clear written instructions on the way waste should be managed.

As a minimum, a healthcare waste policy should contain:

- **A clear policy statement, outlining the aims of the policy;**
- **Legal and statutory obligations;**
- **Current waste management arrangements;**
- **An outline of who has waste management responsibilities and the lines of accountability;**
- **Arrangements for implementing the policy;**
- **Sources of further information and guidance e.g. Trust healthcare waste guidance.**

Ownership of the policy needs to be at senior managerial level. In order to be successful, the policy needs to address all key issues and be actively supported by those involved in each stage of the management of the waste. The responsibilities of line managers and others need to be clear, and the waste management arrangements need to be properly monitored and audited. The existence of a policy should not be assumed to be an indication of practice. Practice can only be determined and monitored by robust audit procedures.

It is recommended that the organisation has access to a dedicated qualified waste manager to co-ordinate and manage all healthcare waste and other waste management activities.

In order to be used effectively the healthcare waste policy should link with other healthcare policies and guidance and should be used as the basis for staff training and awareness.

The contents of this guidance document address the key issues to be included within the healthcare waste policy document.

4.0 Regulatory Definitions and Classifications

This section of the document outlines the definitions and classifications used for healthcare waste in UK Waste, Carriage (transport) and Health & Safety legislation.

Section 5 of this guidance document provides a simplified definition and classification system which complies with the requirements identified in this section.

4.1 Waste Management Definitions and Classifications

Waste regulation requires the classification of waste on the basis of hazardous characteristics and point of production.

4.11 Clinical Waste

The definition of clinical waste has historically been used to describe those wastes produced from healthcare and similar activities that pose a risk of infection or may prove hazardous. Clinical waste should be segregated from other wastes and treated/disposed of appropriately in suitably licensed facilities on the basis of the hazard it poses.

The current legal definition of clinical waste in the UK is taken from The Controlled Waste Regulations 1992, issued under the Environmental Protection Act 1990. It has remained unchanged since it was first issued under the Collection and Disposal of Waste Regulations 1988, issued pursuant to the Control of Pollution Act 1974.

Clinical waste is defined as:

(a)“..any waste which consists wholly or partly of human or animal tissue, blood or other bodily fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and

(b) any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it.”

The relationship between the definition of clinical waste and hazardous waste definitions is explained in sections 4.13 to 4.15 of this report.

4.12 European Waste Catalogue

Recent regulatory changes, notably The Landfill (England and Wales) Regulations 2002, The Hazardous Waste (England and Wales) Regulations 2005 and List of Waste (England) Regulations 2005, require producers to adequately describe their waste using both a written description and the use of the appropriate European Waste Catalogue (EWC) code(s).

The EWC is a list of wastes produced by the European Commission in accordance with the European Waste Framework Directive (75/442/EEC) to provide common terminology for describing waste throughout Europe. The EWC list is reviewed periodically and incorporates the European Hazardous Waste List pursuant to the Hazardous Waste Directive 91/689/EEC.

The EWC is colour-coded to aid identification of hazardous waste. **Absolute entries*** (shown in red) in the catalogue are deemed to be hazardous regardless of their composition or concentration. **Mirror entries** (shown in blue) are those which are recognised as having the potential to be hazardous and require an assessment of their composition and concentration. **Non-hazardous wastes** are shown in black. A full copy of the EWC can be found in Appendix A. The EWC categorises waste into 20 chapters; each chapter is linked to a production sector.

Healthcare wastes are listed in Chapter 18 of the EWC, however, producers should be aware that healthcare premises produce a wide variety of wastes and reference should be made to other relevant EWC chapters.

Within each chapter, wastes are described using 6 digit numerical codes, the first two digits of the code relate to the EWC chapter, the second two digits relate to any sub-grouping within the chapter, and the final two digits are unique to the waste.

The table below provides a list of all Chapter 18 (Healthcare Waste) EWC codes.

EWC Code	Description of Waste
18 01 XX	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 01	Sharps except (18 01 03)
18 01 02	Body parts and organs including blood bags and blood preserves, (except 18 01 03*)
18 01 03*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 04	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection, e.g. dressings, plaster casts, linen, disposable clothing
18 01 06*	Chemicals consisting of dangerous substances
18 01 07	Chemicals other than those listed in 18 01 06*
18 01 08*	Cytotoxic and cytostatic medicines
18 01 09	Medicines other than those mentioned in 18 01 08*
18 01 10*	Amalgam waste from dental care

EWC Code	Description of Waste
18 02 XX	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 01	Sharps except (18 02 02)
18 02 02*	Waste whose collection and disposal is subject to special requirements in order to prevent infection
18 02 03	Waste whose collection and disposal is not subject to special requirements in order to prevent infection
18 02 05*	Chemicals consisting of dangerous substances
18 02 06	Chemicals other than those listed in 18 02 05*
18 02 07*	Cytotoxic and cytostatic medicines
18 02 08	Medicines other than those mentioned in 18 02 07*

*Hazardous Waste List Entries

The use of the EWC has led to a change in the classification of infectious and medicinal waste in the UK. A number of entries in Chapter 18 of the EWC are classified as hazardous waste.

4.13 Hazardous Waste

The Hazardous Waste (England and Wales) Regulations 2005 and the List of Waste (England) Regulations 2005 define and regulate the management of hazardous waste in England. These Regulations, amongst other things, require producers of hazardous waste to notify (register) with the Environment Agency (see section 13.31).

The Regulations do not provide comprehensive guidance on the classification of waste. However, guidance is provided by the UK environmental regulatory agencies.

4.14 Hazardous Waste Guidance WM2

The UK environmental regulatory agencies, i.e. Environment Agency (EA), Scottish Environment Protection Agency (SEPA) and the Environment and Heritage Service (EHS) in Northern Ireland, have produced a joint guidance document on the interpretation, definition and classification of hazardous waste, titled: WM2.

WM2 is available from the Environment Agency web site:

www.environment-agency.gov.uk/commondata/acrobat/1_haz_waste_intro.pdf

WM2 provides guidance on the classification of **absolute*** and **mirror** entries in the EWC in relation to the 14 hazard groups identified in the Hazardous Waste Regulations 2005. The 14 hazard groups originate from the Hazardous Waste Directive and are shown below:

H1	Explosive
H2	Oxidising
H3A	Highly Flammable
H3B	Flammable
H4	Irritant
H5	Harmful
H6	Toxic
H7	Carcinogenic
H8	Corrosive
H9	Infectious
H10	Toxic for Reproduction
H11	Mutagenic
H12	Substances that release toxic gases
H13	Substances capable of yielding substances listed above
H14	Ecotoxic

Appendix C of the WM2 guidance provides comprehensive guidance on the classification of waste in each of the hazard groups. The following sections provide a summary of the WM2 guidance with respect to infectious, medicinal and amalgam healthcare wastes.

4.15 Infectious Hazardous Wastes

The Hazardous Waste Regulations 2005 define infectious as:

H9 Infectious	Substances containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in man or other living organisms.
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WM2 provides additional guidance on the interpretation of this definition in the UK by reference to the need for specialist treatment or disposal, described in WM2 as '*special requirements in order to prevent infection*'.

Waste defined as clinical waste on the basis of the infection risk posed should be considered hazardous infectious waste as the waste requires specialist treatment/disposal.

Absolute EWC entries for Infectious Wastes (Hazardous Property H9) are only found in Chapter 18 of the EWC. The relevant EWC codes for infectious waste are shown below.

EWC Code	Description of Waste
18 01 XX	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 03*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 XX	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 02*	Waste whose collection and disposal is subject to special requirements in order to prevent infection

Q: Do you agree with the recommendation that clinical waste is redefined as hazardous infectious waste? If not, please give explanations

4.16 Medicinal Hazardous Wastes

The EWC has entries for medicinal wastes in both Chapter 18 (Healthcare Waste) and Chapter 20 (Municipal Waste) as shown below.

EWC Code	Description of Waste
18 01 XX	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 08*	Cytotoxic and cytostatic medicines
18 01 09	Medicines other than those mentioned in 18 01 08*
18 02 XX	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 07*	Cytotoxic and cytostatic medicines
18 02 08	Medicines other than those mentioned in 18 02 07*
20 XX XX	Municipal waste (household waste and other similar commercial, industrial and institutional wastes (including separately collected fractions))
20 01 31*	Cytotoxic and cytostatic medicines
20 01 32	Medicines other than those mentioned in 20 01 31

Medicinal wastes are classified into two categories:

- Cytotoxic and cytostatic medicines;
- Medicines other than those classified as cytotoxic and cytostatic.

Only cytotoxic and cytostatic medicines are classified as hazardous waste. However, other (non-cyto) medicinal waste may require specialist treatment/disposal.

The joint agency guidance document: WM2 does not provide any clarification on the classification of these wastes. However, future guidance is expected, and on the basis of that, a proposed classification system has been suggested by the authors of this document in section 5.1.

4.17 Amalgam Hazardous Wastes

The only entry for amalgam waste is in Chapter 18 (Healthcare Waste) of the EWC and it is classified as a hazardous waste.

EWC Code	Description of Waste
18 01 XX	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 10*	Amalgam waste from dental care

All waste materials containing or contaminated with mercury are classified as hazardous waste.

4.2 Transport Definitions and Classifications

The Carriage Regulations do not specifically regulate waste materials. They apply to all dangerous goods regardless of whether a material is waste or not. Goods are assessed on their hazardous characteristics and, if applicable, are classified into one of nine Classes of dangerous goods. The nine Classes are shown, along with examples of healthcare waste in each, in Appendix B. Once goods have been classified into their appropriate Class, this information is used to identify appropriate packaging and labelling requirements. The packaging and labelling in relation to carriage regulation is discussed in greater detail in section 8.

4.21 Classification of Infectious Waste for the Purpose of Transport


Infectious substances are classified in Class 6.2 of ADR. Infectious wastes are classified into two categories: Category A and Category B. Full details can be found in chapter 2.2.62 of ADR

Category A	An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease to humans or animals.
Category B	An infectious substance which does not meet the criteria for inclusion in category A.

Waste which is known or suspected to be contaminated with pathogens presenting the most severe risk of infection is classified as a Category A waste, examples of Category A pathogens can be found in Appendix B. Category A waste includes infectious waste from highly infectious diseases such as the Ebola virus and cultures of certain infectious diseases including *Clostridium botulinum* and *Mycobacterium tuberculosis*. With the exception of certain laboratory wastes very little Category A waste will be produced from healthcare premises

within the UK. The vast majority of infectious waste produced from the healthcare sector will be classified as Category B.


The table below shows the classifications used for infectious waste in Carriage Regulation:

	Carriage (Transport) Classification	
Infectious Waste Human Healthcare	CAT A UN2814	Class 6.2 (Infectious) 
	CAT B UN3291	
Infectious Waste Animal Healthcare	CAT A UN2900	
	CAT B UN3291	

Section 8 provides further details of the use of UN Numbers (UN) and the packaging and labelling of this waste stream.

4.22 Classification of Medicinal Waste for the Purpose of Transport

Medicinal wastes are classified in Class 6.1 of ADR as toxic substances. The table below shows the classifications used for medicines and medicinal waste in Carriage Regulation:

UN Description	Carriage (Transport) Classification	
Medicine Liquid Toxic	UN 1851	Class 6.1 (Toxic) 
Medicine, Liquid Flammable Toxic	UN3248	
Medicine Solid Toxic	UN3249	

Section 8 provides further details of the use of UN Numbers (UN) and the packaging and labelling of this waste stream.

4.3 Definitions and Classifications for Health and Safety

Health and safety legislation does not contain any specific waste definitions or classifications. However, the regulations (notably COSHH) require those dealing with hazardous and potentially infectious materials, (including waste), to assess the risk to both their staff and the public who may come into contact with the material. COSHH specifically requires consideration of the biological agents that may be present and the hazard groups they belong to. Reference should be made to the COSHH Approved Code of Practice and the Approved List of Biological Agents.

4.4 Other Definitions Associated with Healthcare Waste

4.41 Medical Devices

Medical devices are defined in the Medical Devices Regulations 2002.

Medical devices are defined as:

"An instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:

(a) is intended by the manufacturer to be used for human beings for the purpose of:

- (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- (iii) investigation, replacement or modification of the anatomy or of a physiological process, or
- (iv) control of conception;

and (b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device

Infected/Used Medical Devices

Where implanted medical devices have been in contact with infectious bodily fluids and have been assessed to be infectious, they should be classified and treated as infectious waste.

If the device contains hazardous materials or components including nickel cadmium and mercury containing batteries the description of the waste on the consignment note must fully describe the waste and all its hazards. For example, an implanted device with a nickel cadmium battery should be described as:

18 01 03 Infectious Waste containing Nickel Cadmium batteries
[Hazards: Infectious (H9) and Corrosive (H8)]

Disinfected/Unused Medical Devices

Disinfected medical devices should be classified as non-infectious healthcare waste. The description given of the waste must adequately describe the waste and any hazardous characteristics (even if the waste is not classed as hazardous waste).

For example a disinfected device containing a nickel cadmium battery should be described as:

18 01 04 Non Infectious Healthcare Waste containing batteries
[Hazards: Corrosive (H8)]

4.42 Radioactive Waste

This guidance covers the management of low-level radioactive infectious waste produced from healthcare activity. It does not cover the management and disposal of sealed radioactive sources.

Radioactive waste generated from healthcare includes radionuclides used in therapeutic and diagnostic medicine. Generally, this waste is considered to be low-level radioactive waste, this waste is sub-divided into three categories:

- Long half-life: ^3H , ^{14}C ;
- Radioiodines: ^{123}I , ^{125}I , ^{131}I (any mixed waste containing radioiodine will be in this category);
- Other Beta/Gamma emitters: ^{89}Sr , ^{35}S , ^{32}P , ^{51}Cr , ^{201}Tl , ^{111}In , ^{67}Ga , $^{99\text{m}}\text{Tc}$, ^{57}Co , ^{75}Se , ^{65}Zn , ^{59}Fe , ^{22}Na , ^{24}Na , ^{45}Ca .

The UK environmental regulatory agencies (EA, SEPA, and EHS) regulate the storage and use of radioactive material in hospitals. Small users of radioactive sources, (including hospitals) require authorisation to discharge. The Environment Protection Act 1990 gives the regulators authorisation to permit discharges, and discharge limits are set under the Radioactive Substances Act 1993.

Radioactive wastes are not included in the EWC. However, waste listed in the EWC contaminated with radioactive waste should be classified using the most appropriate EWC code(s) and the written description of the waste should describe the type and level of radioactive contamination.

Radioactive Waste and Carriage

Radioactive waste should be labelled with the appropriate class according to its hazard characteristics in accordance with the Radioactive Materials (Road Transport) Regulations 2002. Radioactive wastes are classified as Class 7 substances. The hazard warning diamond used may vary, based on the isotope and the level of hazard posed. An example of the hazard warning diamond is shown below:



Radiation Protection Adviser

The Ionising Radiation Regulations 1999 specify that a Radiation Protection Adviser (RPA) should be appointed to advise on the use and management of radioactive materials. The RPA should work with healthcare staff and a DGSA to ensure the safe management and transfer of radioactive waste.

4.43 Diagnostic Specimens

Diagnostic specimens are defined as:

Any human or animal materials, including, but not limited to, excreta, blood and its components, tissue and tissue fluids being carried for diagnostic or investigation purposes, but excluding live infected animal.

Diagnostic specimens are not waste items and are not subject to waste management controls.

Diagnostic specimens are considered dangerous goods for the purpose of carriage and are classified in Class 6.2 (Infectious) as UN3373.

4.44 Anatomical Waste

The EWC lists anatomical waste with blood bags and blood preserves as shown below:

EWC Code	Description of Waste
18 01 XX	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 02	Body parts and organs including blood bags and blood preserves (except 18 01 03)
18 01 03*	Wastes whose collection and disposal is subject to special requirements in order to prevent infection

However, it is recognised that producers may wish to segregate these wastes at source because they often have differing disposal requirements.

For the purpose of this guidance document the definition of anatomical waste includes: body parts or other recognisable anatomical items which may be offensive to those who come into contact with it.

Anatomical waste may often be classified as infectious waste due to its contamination with potentially infectious bodily fluids. This guidance document recommends 'best practice' as classifying all anatomical waste as infectious (18 01 03*) because all anatomical waste requires specialist disposal in suitably authorised facilities.

It is recognised that the disposal of teeth from dental premises is unlikely to cause offence and therefore Dental Practitioners may treat this as a non-anatomical infectious waste. Dental Practitioners must ensure that all wastes are treated appropriately and teeth containing amalgam should be segregated and sent for appropriate recovery/disposal.

5.0 Unified Definitions and Classifications

This guidance document introduces a new methodology for identifying and classifying infectious and medicinal waste which complies with Health & Safety, Carriage and Waste Regulation. The new methodology is described as the 'Unified' approach and the following section provides details of this approach for infectious and medicinal waste classification.

The Unified approach has been developed to help waste producers comply with regulatory requirements. Use of the Unified approach is not mandatory but is considered best practice. Compliance with the Unified approach will ensure that producers comply with and go beyond the Regulatory requirements.

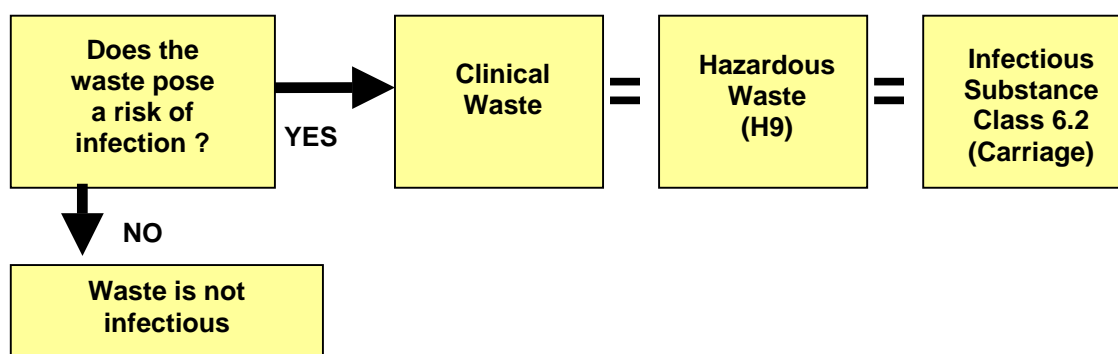
Q: Do you agree with the methodology proposed? If not, identify what alternative approach or methodology would be more acceptable.

5.1 Unified Definition of Infectious Waste

In an effort to produce a single classification system for infectious waste; the following definitions and classifications have been considered:

- The definition of Clinical Waste given in The Controlled Waste Regulations 1992;
- The Hazardous Waste Regulations 2005 (and WM2 guidance);
- The definition of infectious substances given in ADR.

The diagram below shows the relationship between the definitions and classifications.



If an item of healthcare waste is considered to pose a risk of infection it should be considered clinical waste, it should be classified as hazardous waste and should be transported as an infectious substance.

Only infectious waste requires treatment at specialist facilities. Therefore if waste is being sent to a facility to render it safe, disinfect, sterilise or incinerate it due to its infectious nature, the waste should be considered infectious waste.

5.11 Identification of Infectious Waste

Infectious waste is classified as waste which may pose a risk of infection to a human or animal. The classification of infectious waste does not rely on the use of pathogen classification groups and waste should be considered infectious even if the resulting infection would be considered 'minor'.

In order to help clinicians and carers identify potentially infectious waste at the point of production the following simplified assessment has been introduced. The assessment is based on the contamination of the waste materials with bodily fluids. The assessment is applicable to both wet and dried fluids. The assessment should be used to help staff undertake risk assessments and has not been designed to replace risk assessment or clinical judgement.

The table below shows two sets of bodily fluids.

<p style="text-align: center;">Column 1 Infectious Bodily Fluids</p>	<p style="text-align: center;">Column 2 Non- Infectious Bodily Fluid</p>
<p style="text-align: center;">Blood; Semen Vaginal Secretions Cerebrospinal ; Synovial ; Pleural; Peritoneal; Pericardial; Amniotic</p>	<p style="text-align: center;">Faeces; Nasal Secretions; Sputum; Tears; Urine; Vomit</p>
<p>It should be noted that waste contaminated with the fluids (liquid or dried) listed in Column 2 may be considered infectious if they contain visible blood or there has been a clinical assessment that the source patient has an infection that might be transmitted via the waste e.g. an infection pathway exists.</p> <p>Examples of known infection pathways include:; faeces known or suspected to be contaminated with <i>enteric pathogens e.g. Salmonella or shigella</i> or vomit from a patient assessed to have an acute vomiting virus.</p>	

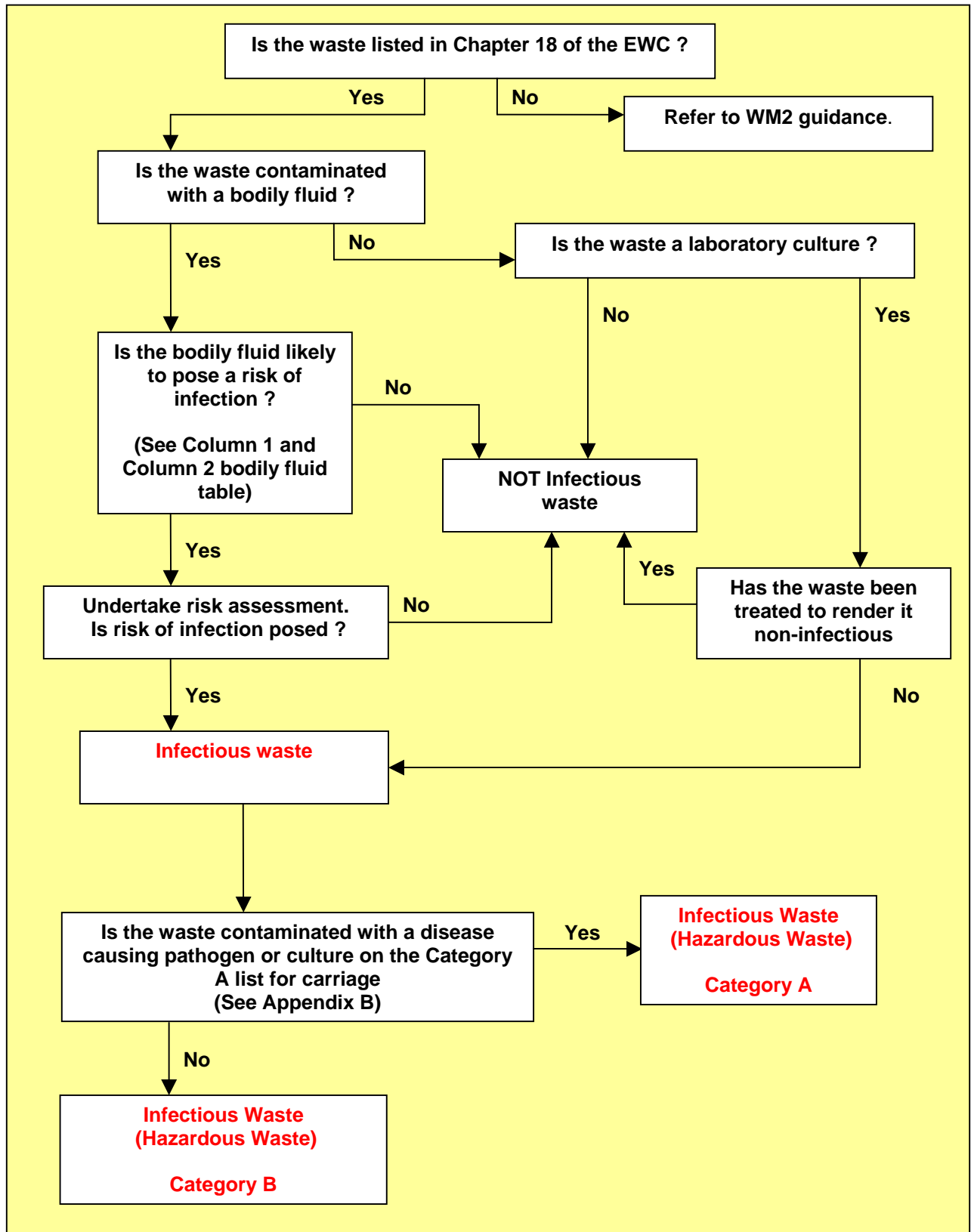
The fluids shown in Column 1 may present a risk of infection and a risk assessment should always be carried out on waste contaminated with these fluids to determine if the waste is infectious. The fluids shown in Column 2 do not normally present a risk of infection and wastes contaminated with these fluids will not normally be classified as infectious waste unless visible blood is present or the source patient has an infection that might be transmitted via the waste.

In general, only waste generated from healthcare practise undertaken by a suitably qualified healthcare practitioner will be considered as infectious waste. Wastes from domestic minor first aid and self-care, of a type that does not involve recourse to a healthcare practitioner, is not included within the scope of this assessment. Similar municipal type wastes from industrial and commercial premises are also excluded. Therefore, soiled waste such as sanitary products and plasters are not considered to be infectious unless specific advice is given to the contrary by a healthcare practitioner.


It is acknowledged that wastes contaminated with non-infectious bodily fluids (listed in Column 2) are capable of causing offence and therefore require appropriate packaging to alert those in the waste management chain of the contents. It is recommended that such wastes be classified as **offensive waste**. Guidance on the management of offensive waste can be found in section 5.3.

A flow diagram has been produced to help producers identify and classify infectious waste appropriately (shown overleaf).

Assessment and Classification of Infectious Waste



The table below shows the classification and identification codes that should be used for infectious waste.

	Waste Classification (EWC)	Carriage (Transport) Classification	
Infectious Waste - Human Healthcare	18 01 03*	CAT A UN2814	Class 6.2 (Infectious) 
		CAT B UN3291	
Infectious Waste – Animal Healthcare	18 02 02*	CAT A UN2900	
		CAT B UN3291	

5.2 Unified Definition of Medicinal Waste

Medicinal waste encompasses licensed medicinal products of any type, and residues in bottles, vials and ampoules that are not sharps. Medicinally contaminated syringes, needles and broken glass medicinal ampoules are considered to be sharps.

Medicinal wastes are listed in both Chapter 18 (Healthcare Waste) and Chapter 20 (Municipal Waste) of the EWC. The EWC differentiates between cytotoxic and cytostatic medicines and all other medicines. Only cytotoxic and cytostatic medicines are considered to be hazardous waste.

The terms cytotoxic and cytostatic are not clarified in the Hazardous Waste Regulations 2005 or the joint regulatory guidance: WM2. The term cytotoxic has often been referred to in relation to the classification of medicinal products associated with the treatment of malignant disease and immunosuppression, often referred to as medicines listed in chapter 8 of the British National Formulary (BNF). However, reference to BNF Chapter 8 does not include all cytostatic medicinal products which may be listed in a number of chapters of BNF.

Based on research in the USA and adopted by the UK environmental regulatory agencies (EA, SEPA and EHS), this guidance document recommends the classification of cytotoxic and cytostatic medicinal waste on the basis of their hazardous characteristics.


A cytotoxic and cytostatic medicine is a medicinal product with a chemical risk phrase above the threshold concentration of one or more of the hazardous properties shown in the table below:

H6	Toxic
H7	Carcinogenic
H10	Toxic for Reproduction
H11	Mutagenic

This assessment is determined solely by assessment of the medicinal products in the form supplied by the manufacturer or distributor, and does not therefore consider the effects of any subsequent dilution that may occur during routine use. Further guidance on the assessment of these hazardous properties may be obtained from Hazardous Waste guidance: WM2.

Guidance should be sought from the manufacturers of medicinal products with regard to their hazard characteristics. The use of data sheets in local pharmacy practices may be used to classify products. However, ideally manufacturers of products should be encouraged to provide this information.

The table below shows the classification and identification codes that should be used for infectious waste.

Waste Classification (EWC)	UN Description	Carriage (Transport) Classification	
Human Healthcare: Cytotoxic & Cytostatic 18 01 08* 18 01 09 Other Medicines	Medicine Liquid Toxic	UN 1851	Class 6.1 (Toxic) 
	Medicine Liquid Flammable Toxic	UN3248	
Animal Healthcare: Cytotoxic & Cytostatic 18 02 07* 18 02 08 Other Medicines	Medicine Solid Toxic	UN3249	

Products containing alcohol or flammable propellant gases e.g. aerosols, may also be classified in Class 3 (flammable liquids) or Class 2 (flammable gases).

5.3 Offensive Waste

The term 'offensive waste' is introduced in this guidance to describe wastes which are non-infectious, do not require specialist treatment or disposal but may cause offence to those coming into contact with it. Offensive waste includes wastes previously described as human hygiene waste and sanpro waste.

Examples of offensive wastes include:

- Incontinence and other waste produced from human hygiene;
- Sanitary wastes;
- Disposal medical/veterinary items and equipment which do not pose a risk of infection including, gowns, plaster casts, etc.
- Animal faeces and soiled animal bedding.

Robust risk assessment protocols are required when offensive waste is segregated from infectious waste in a healthcare setting. Staff segregating waste must be provided with clear instructions on the segregation process and should be provided with appropriate training. Colour-coded waste receptacles should be supplied for each waste stream.

The following EWC codes should be used to identify offensive waste:

Offensive waste produced directly as a result of healthcare activities should be classified in Chapter 18 of the EWC as follows:

EWC Code	Description of Waste
18 01 XX	Wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 04	Wastes whose collection and disposal is not subject to special requirements in order to prevent infection, e.g. dressings, plaster casts, linen, disposable clothing.
18 02 XX	Wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 03	Waste whose collection and disposal is not subject to special requirements in order to prevent infection.

Offensive waste produced from other (non-healthcare) activities should be classified in Chapter 20 of the EWC as follows:

EWC Code	Description of Waste
20 XX XX	Municipal waste (household waste and other similar commercial, industrial and institutional wastes (including separately collected fractions))
20 01 99	Other fractions not otherwise specified

Offensive waste from non-healthcare activities includes feminine hygiene bins, and nappy bins in commercial and industrial premises e.g. shopping malls and offices. The following written description should be used to describe this waste on a Duty of Care Transfer Note:

20 01 99 Sanitary/Human/Animal Hygiene Waste

Q: Do you agree with the benefits of introducing an “offensive waste” stream?

6.0 Waste Audits

6.1 Purpose of Audit

Waste Audits are a useful tool in assessing the composition of a waste stream and for monitoring waste segregation and minimisation schemes. Audit results identify the type and quantity of waste produced; this information can be used to develop and influence waste management policies and procedures. Audits also provide useful information on the composition of waste produced and the results may be used to identify appropriate re-use or recycling options and opportunities to minimise waste by amending purchasing policies.

Audits play a vital role in demonstrating compliance with regulatory standards. Waste producers are required, in line with the Duty of Care, to ensure that waste is effectively segregated to ensure that the waste is treated and disposed of appropriately.

Documented evidence from waste audits showing effective segregation demonstrates that the producer is complying with regulations and is considered best practice.

6.2 Frequency of Audits

At a minimum, audits are recommended prior to developing or updating waste management procedures and at routine intervals to monitor compliance with waste segregation schemes. Annual audits provide a 'snap-shot' of waste management practices, whilst more frequent audits allow producers to monitor the effectiveness of waste segregation and minimisation initiatives and to take action to remedy non-compliances as soon as practically possible.

It is neither practical nor reasonable to expect healthcare producers to audit all waste produced on a site at the same time. Therefore, the use of random audits covering all aspects of waste management is considered best practice. In order to demonstrate compliance all waste management activities should be audited at a frequency no less than once per year.

6.3 Scope of Audits

Audits should cover (at minimum) the following waste types:

- Infectious Waste and Sharps*
- Offensive Waste
- Domestic Waste
- Kitchen Waste
- Separately Collected Fractions e.g. recyclables

* Audit procedures for hazardous waste should take into account the specific risk posed and the audit procedure should be adapted to minimise exposure to the waste. Where exposure occurs suitable personal protective equipment must be supplied.

6.4 Audit Techniques

There are a number of methods that can be used to audit a waste stream. The type and effectiveness of the audit undertaken will be dependent on the nature of the waste stream and the purpose of the audit. In order to audit the entire waste stream more than one audit method may be required. An audit protocol containing four audit tools is provided below.

The table below provides a guide to the minimum frequency with which each part of audit should be conducted.

Type of Audit	Minimum Frequency	Application				
		Sharps Boxes	Infectious Waste	Cytotoxic Materials	Waste Medicines	Offensive Waste
Audit Observation and Recoding of Practice	Annual	✓	✓	✓	✓	✓
Observation of Waste Containers	Quarterly	✓	✓	✓	✓	✓
Staff Questionnaire	As needed	✓	✓	✓	✓	✓
Detailed Examination of Waste	Annual	✗	✗	✗	✓	(✓)

The audit should encompass

- The full range of waste containers in use;
- The full range of departments where waste is produced; and
- All staff who may produce waste.

Observation and Recording of Practice

Audits should involve a review of staff waste management practices, and in particular the effectiveness of segregation procedures. The audit entails the observation and recording of each waste item as it is placed into a container. The final step in the audit is to confirm that the paperwork accompanying the waste when it leaves the premises reflects the audit findings. This applies to all waste types, including hazardous wastes, and should be carried out at a minimum frequency of once per annum.

Observation of Waste Containers

This provides a mechanism of spot checks intended to underpin the Observation and Recording of Practice.

In use containers are visually inspected without removing the waste from its container. For example; the contents of a sharps container can be viewed from the aperture or opening of the container.

This applies to all waste types, including hazardous wastes, and should be carried out a minimum frequency of once per quarter

Detailed Examination of Waste

Detailed waste analysis is used to determine the nature and composition of waste materials and involves the manual sorting of waste to determine the effectiveness of segregation procedures.

This procedure must only be carried out in controlled conditions in line with health and safety requirements. All those involved should ensure that the appropriate personal protective equipment is used. The use of detailed examination of the waste should not be used for hazardous wastes including infectious waste, cytotoxic and cytostatic wastes and sharps.

Staff Questionnaire

Staff understanding and practice can be audited by the use of questionnaires. These can be used to target specific areas or may be used randomly. Questionnaires may be used to review staff practice for all waste types, including hazardous waste. The main use of this tool is to identify issues for, and to establish, staff awareness.

Note: Questionnaires do not provide sufficient information, with regard to the effectiveness of segregation practice or waste composition, for use in completing waste documentation or in demonstrating compliance.

6.5 Undertaking Audits

Audits must only be undertaken by staff who have been trained in the audit procedure and are fully aware of the risk and hazards posed by the audit protocol. The audit protocol should be stated in the waste management policy.

A detailed method statement should be produced for each audit tool clearly stating the following:

- Who should undertake the audit;
- What is included within the audit;
- How the audit should be undertaken;
- The method of recording and reporting the findings of the audit;
- The management responsibility and mechanism to act on the findings.

The method statement should also state any inherent risks and the control measures required, for example Personal Protection Equipment (PPE) required.

Use of Contractors

Commercial contractors and consultants may be used to undertake waste audits. Producers are advised to consider the following:-

- The producer is responsible for the health and safety of contractors working on their site (see section 2.2.);
- Waste removed from the site for the purpose of an audit should comply with relevant waste and transport legislation;
- The organisation conducting the audit should not be affected by the outcome. Conflicts of interest should be avoided.

7.0 Waste Segregation

Segregation of waste at the point of production into suitable, colour-coded packaging is vital to good waste management. Health & Safety, Carriage and Waste Regulation require that waste is handled, transported and disposed of in a safe and effective manner. The following colour-coded waste segregation guide represents best practice only and ensures, at minimum, compliance with current regulation.

The following waste types are included in this segregation guide:

- Infectious radioactive wastes;
- Non-infectious radioactive wastes;
- Sharps contaminated with cytotoxic/cytostatic products;
- Infectious waste contaminated with cytotoxic/cytostatic products;
- Infectious waste;
- Amalgam waste;
- Cytotoxic and Cytostatic waste;
- Other medicinal wastes,
- Offensive wastes;
- Domestic wastes;
- Large equipment, e.g. mattresses;
- Implanted/infectious medical devices.

7.1 Colour Coding

Proper segregation of different types of waste is critical to safe management of healthcare waste and helps control management costs. The use of colour-coded containers is key to good segregation practice.







Colour Coding by Waste Management Option

The following colour-coded segregation system identifies and segregates waste on the basis of waste classification and suitability of treatment/disposal options. The use of this colour coding system is not mandatory and is not specified in regulations. Producers may wish to adopt this system to aid the identification and segregation of their waste. By adopting the best practice system, standardisation can be achieved across the UK.

It should be noted that reference is made to the minimum required standard of waste treatment/disposal. However, waste may be sent to alternative treatment/disposal methods which operate to an equivalent or higher standard.

Q: Do you agree with the benefits of a nationally based system of colour-coded packaging? If not, please suggest any recommendations for an alternative approach.


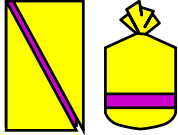
The table shown below summarises the colour coding system.

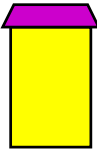
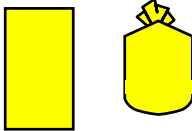

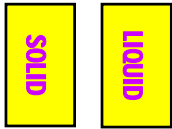
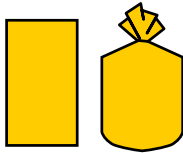
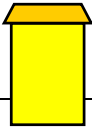
Colour	Description
	Infectious Waste Minimum treatment/disposal required is incineration in a suitably licensed or permitted facility.
	Infectious Waste Minimum treatment/disposal required is to be 'rendered safe' in a suitably licensed or permitted facility.
	Cytotoxic/Cytostatic Waste Minimum treatment/disposal required is incineration in a suitably licensed or permitted facility.
	Offensive Waste* Minimum treatment/disposal required is landfill in a suitably licensed or permitted site. This waste should not be compacted in un-licensed/permitted facilities.
	Domestic Waste Minimum treatment/disposal required is landfill in a suitably licensed or permitted site.
	Amalgam Waste For recovery.



* The use of yellow/black for offensive waste was chosen as these colours have historically been universally used for the sanitary/offensive waste stream.

7.2 Colour-coded Segregation Chart

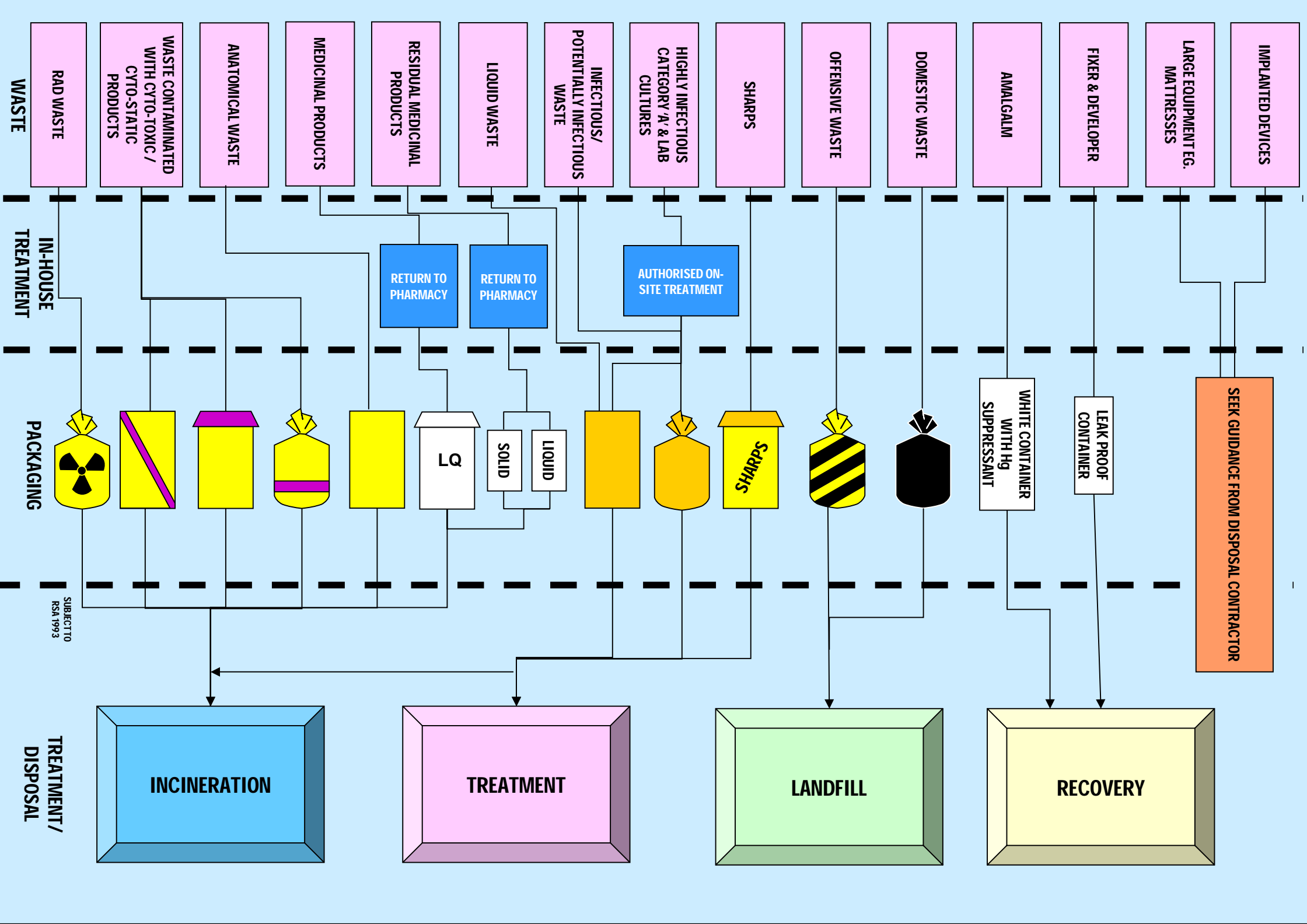
The following charts identify the type of packaging and packaging colour required for each waste stream. The chart assumes that the packaging meets the requirements of Carriage Regulations (UN compliant) where appropriate. Section 8 of this document provides guidance on compliant packaging.

Waste Receptacle	Description	Example Contents	Minimum Treatment/Disposal
	Healthcare waste contaminated with radioactive material	Dressings, tubing, etc from treatment involving low level radioactive isotopes	Incineration in hazardous waste incineration facility subject to RSA 1993
	Infectious waste contaminated with cytotoxic and /or cytostatic medicinal products	Dressings/tubing from cytotoxic treatment	Hazardous waste incineration

	Sharps contaminated with cytotoxic and /or cytostatic medicinal products	Sharps used to administer cytotoxic products.	Hazardous waste incineration
	Infectious waste requiring incineration including anatomical waste	Theatre waste	Hazardous waste incineration
	Amalgam waste	Dental amalgam wastes	Recovery
	Residual medicines NOT in original packaging	Waste tablets not in foil pack or bottle	Hazardous waste incineration
	Infectious and potentially infectious waste and autoclaved laboratory waste	Soiled dressings	Licensed/permitted treatment facility
	Sharps not contaminated with cyto products	Sharps from phlebotomy	Licensed/permitted treatment facility

	<p>Offensive Waste</p>	<p>Human hygiene waste. and Non-infectious disposable equipment, bedding and plaster casts</p>	<p>Landfill</p>
	<p>Domestic Waste</p>	<p>General refuse, including newspapers, flowers, etc</p>	<p>Landfill</p>

Views are sought on the practicality of segregating sharps waste contaminated with cytotoxic/cytostatic medicinal products and sharps boxes not contaminated with cyto-medications. Suggestions are sought as to how waste products can demonstrate effective waste segregation.



IMPLANTED DEVICES

LARGE EQUIPMENT EG. MATTRESSES

FIXER & DEVELOPER

AMALGAM

DOMESTIC WASTE

OFFENSIVE WASTE

SHARPS

HIGHLY INFECTIOUS CATEGORY 'A' & LAB CULTURES

INFECTIOUS/POTENTIALLY INFECTIOUS WASTE

LIQUID WASTE

RESIDUAL MEDICINAL PRODUCTS

MEDICINAL PRODUCTS

ANATOMICAL WASTE

WASTE CONTAMINATED WITH CYTO-TOXIC / CYTO-STATIC PRODUCTS

RAD WASTE

WASTE

SEEK GUIDANCE FROM DISPOSAL CONTRACTOR

LEAK PROOF CONTAINER

WHITE CONTAINER WITH Hg SUPPRESSANT

SHARPS

LIQUID

SOLID

RETURN TO PHARMACY

RETURN TO PHARMACY

AUTHORISED ON-SITE TREATMENT

INCINERATION

TREATMENT

LANDFILL

RECOVERY

IN-HOUSE TREATMENT

PACKAGING

INCINERATION

TREATMENT

LANDFILL

RECOVERY

INCINERATION

TREATMENT

LANDFILL

RECOVERY

INCINERATION

TREATMENT

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TREATMENT

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RECOVERY

SUBJECT TO RSA 1993

INCINERATION

TREATMENT

LANDFILL

RECOVERY

TREATMENT / DISPOSAL

Additional Comments on Segregation Chart:

Radioactive Waste

Radioactive healthcare wastes are wastes contaminated with low-level radio-isotopes. This waste requires disposal in suitably licensed facilities, which will normally be by incineration.

Purple/Yellow Stream Cyto Waste

Purple/Yellow Stream waste is waste consisting of or contaminated with cytotoxic and/or cytostatic products and requires incineration in suitably licensed or permitted facilities. Healthcare facilities that produce cytotoxic and/or cytostatic waste need to ensure that suitable purple/yellow containers are available for this waste stream including rigid containers for medicinal wastes and/or infectious waste, bags for infectious waste and colour-coded sharps containers.

Anatomical Waste - 'Yellow' Stream Infectious Waste

Yellow stream infectious waste requires disposal by incineration in a suitably licensed or permitted facility. This waste stream includes anatomical waste and may include other wastes which require incineration to comply with national or regional policy including un-autoclaved waste from clinical laboratories. Yellow stream infectious waste, is waste known or suspected to contain pathogens classified in Category B as specified in ADR. Yellow stream infectious waste is hazardous waste and is subject to the controls of the Hazardous Waste Regulations 2005.

Residual Medicinal Waste

Residual medicinal wastes are waste pharmaceuticals no longer in their original packaging. The waste should be placed in UN compliant packages for disposal by incineration. If cytotoxic/cytostatic medicinal residues are present the container should be labelled as such.

Medicinal products

Medicinal products contained within their original packaging (foil packs, bottles, etc) may be packaged in non-UN compliant packages subject to Limited Quantity (LQ) exemptions in line with Carriage Regulations. See ADR 3.4 and SP 601 in ADR 3.3. The limited quantity exemption permits the use of non-UN compliant combination packages up to thresholds specified by the LQ code for the substance concerned. Above this threshold medicinal products must be transported in UN Compliant packages.

All cytotoxic and cytostatic medicinal wastes should be segregated and packaged and disposed of accordingly. Reference should be made to section 5.2 and also to 11.11 for the appropriate disposal route for non-cyto medicinal products.

Liquid Waste

Liquid waste or solidified liquid waste should be placed in a rigid leak proof container for disposal. Many infectious waste treatment facilities require the waste to be solidified prior to removal and producers should seek guidance from their waste management contractor regarding this. Liquid waste may be treated to render it safe in suitably licensed or permitted facilities. However, not all treatment facilities are licensed to accept such waste and producers should seek guidance from their waste contractor regarding the most appropriate disposal route for this waste and use appropriate colour-coded containers.

'Orange' Stream Infectious Waste

Orange stream infectious waste may be treated to render it safe prior to final disposal. Treatment may only take place in a suitably licensed or permitted facility. Orange stream infectious waste is waste known or suspected to contain pathogens classified in Category B as specified in Carriage Regulation and may contain pre-treated (autoclaved) Category A waste. Orange stream infectious waste is hazardous waste and is subject to the controls of the Hazardous Waste Regulations 2005.

Sharps Waste

Sharps are items that could cause cuts or puncture wounds, including needles, syringes with needles attached, broken glass ampoules, scalpel and other blades, infusion sets (the sharps part thereof). Sharps waste does not include syringe bodies (in the absence of a needle), pharmaceutical waste in the form of: bottles, vials, ampoules, tubes or tablets, swabs or other soft clinical waste or anatomical waste. Sharps may be treated to render them safe in suitably licensed or permitted facilities prior to final disposal. However, if the sharps are contaminated with cytotoxic or cytostatic products they should be placed in suitably coloured containers (yellow/purple) and disposed of in suitably authorised incineration facilities.

Category A Infectious Waste

Infectious waste known or suspected to be contaminated with pathogens classified in Category A of ADR should be treated on-site prior to removal to a disposal facility; on-site treatment may include autoclaving in purpose built autoclave facilities. In exceptional circumstances, for example an autoclave malfunction, waste which is normally autoclaved,

should be packaged for carriage and transferred to an incinerator as soon as possible. It should not be allowed to accumulate for more than 24 hours.

Offensive Waste

Offensive waste is defined in section 5.3. Offensive waste is not considered to be an infectious waste, however it may cause offence and should not be compacted unless in accordance with the conditions of a waste management licence or permit. Offensive waste may be landfilled in suitably licensed facilities.

Domestic Waste

Domestic waste is waste similar in nature and composition to waste generated in the home. Domestic waste should not contain any infectious materials, sharps or medicinal products. Domestic waste may be placed in black or clear bags for disposal.

Amalgam

Amalgam waste consists of amalgam in any form and includes all other materials contaminated with amalgam. Amalgam waste should be placed in white rigid containers with a mercury suppressant. Amalgam waste should be sent to suitable licensed or permitted waste management facilities where the waste undergoes a mercury recovery process prior to final disposal.

Fixer and Developer

Fixer and developer may be classified as hazardous waste depending on the type of materials used. Reference should be made to manufacturers' safety data sheets for product information. If appropriate, fixer and developer should be sent to a suitably licensed or permitted waste facility for material recovery. If recovery is not appropriate fixer and developer should be incinerated at suitably licensed or permitted facilities. If the material is recycled or processed on the site of production, for example for silver extraction, the premises may be subject to waste management licensing controls and may require a trade effluent consent.

Large Equipment

Where practicable, equipment should be disinfected prior to disposal. Once disinfected, the waste is not subject to carriage or hazardous waste management controls, however, it is still subject to the duty of care. Where disinfection is not practicable, producers should contact their waste management contractor to establish the best practice packaging and treatment/disposal options.

Implanted Devices

Implanted devices are defined in section 4.41. It is suggested that producers contact their waste contractor to establish the best practice disposal route for implanted devices. It is also recommended that the producer contact the manufacturer of the device to establish whether the device may be disinfected and if a 'take-back' scheme exists for this waste.

Appendix D contains additional information in the form of a waste identification chart which shows the waste, carriage and treatment/disposal options for each type of waste listed.

7.3 Successful waste segregation

In order for segregation systems to be effective, staff need to be provided with:

- Background information and reasons for segregation;
- Appropriate equipment, such as sufficient colour-coded waste containers;
- Clear instruction and training.

Background Information

Background information should be provided to staff in order for them to fully understand why waste segregation is required. Information can be made available to staff in a number of ways including the use of posters, training materials and information leaflets.

Appropriate Equipment

For segregation systems to work effectively, it is important that staff are provided with the necessary equipment including appropriate colour-coded waste receptacles and sack holders. The location of waste receptacles is important, as they must be positioned in locations that meet the requirements of work practice. Staff are likely to adapt with ease to new segregation systems if the design of the system means that staff actions are intuitive. If the actions required are time consuming or laborious, staff may struggle to comply with the system, resulting in the inappropriate segregation of waste.

The following issues should be considered in the design and supply of container systems for waste segregation:

- Waste should be placed in waste receptacles/sacks in holders, or other appropriate containers, as close to the point of production as possible;
- Receptacles/sacks should be replaced at minimum daily or when sacks are $\frac{3}{4}$ full;
- Receptacles should be securely sealed, the use of plastic tie closures is recommended for clinical waste sacks;

- Labelling of sacks to indicate their origin, for example by coding on the sack itself, by suitable permanent marker, by a label showing clearly the name of the hospital and the department, or by pre-printed self-adhesive labels or tape;
- Collections should be at an appropriate frequency.

Staff Training

Clear information, instruction and training on categorising waste needs to be provided for everyone working in areas where healthcare waste arises. It is helpful if posters showing the different waste streams and types of waste are displayed at appropriate locations.

Implementing a system for segregation of healthcare waste streams may involve significant changes in waste management practices. Preparation is essential:

- To ensure that staff are involved in the process of change;
- To ensure that non-clinical (i.e. domestic type) wastes are redirected from the healthcare infectious waste stream, to minimise the risk of system failure.

All staff who come into contact with healthcare waste should receive training, ideally this should be specific to their job function. Section 16 of this guidance document provides further information on training.

Evaluation and Monitoring

It is essential that the procedures used for segregating waste are monitored and evaluated on a regular basis. Waste audits are an ideal way of evaluating the success of segregation procedures. Once the results of the audit are known it is important to give feedback to staff on how the arrangements are working.

7.4 Frequency of Collection

Where waste accumulates in small quantities daily, the interval between collections ought to be as short as reasonably practicable. With regard to infectious waste, excluding sharps, the collection period should be no less than once a week, unless the waste is refrigerated. It is recommended that sharps containers are exchanged at regular intervals no less than 3 months.

Arrangements should be made to routinely transport waste from ward level to a storage area pending collection by a waste contractor. See section 10.1 for internal transport and section 9 for storage.

If waste is permitted to accumulate, producers should seek guidance from the appropriate environmental regulatory agency (e.g. Environment Agency) regarding the need for a waste management licence.

8.0 Packaging and Labelling

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004 (as amended) (the Carriage Regulations) specify the packaging and labelling requirements for all dangerous goods (including waste materials). The carriage regulations make direct reference to the international agreement on dangerous goods known as ADR. ADR requires that all dangerous goods be identified using a four digit number (UN Number). Appendix B contains a look-up chart showing the UN Numbers for healthcare waste covered in this document. All dangerous goods are assigned to one of nine classes in ADR; a description of each of the classes is also shown in Appendix B.

A qualified Dangerous Goods Safety Advisor (DGSA) can provide advice with regard to the classification of materials by UN Number and class. However, there is no regulatory requirement for healthcare waste producers to use a DGSA.

8.1 Packaging Requirements

Once the UN Number of a material is known, section 3.2 of ADR provides information on the packaging group, packaging instruction and any special packaging provisions that apply.

8.11 Packing Groups

Section 2.1 of ADR assigns packaging groups to dangerous goods in accordance with the degree of danger they present.

Packing Group I - High danger

Packing Group II - Medium danger

Packing Group III - Low danger

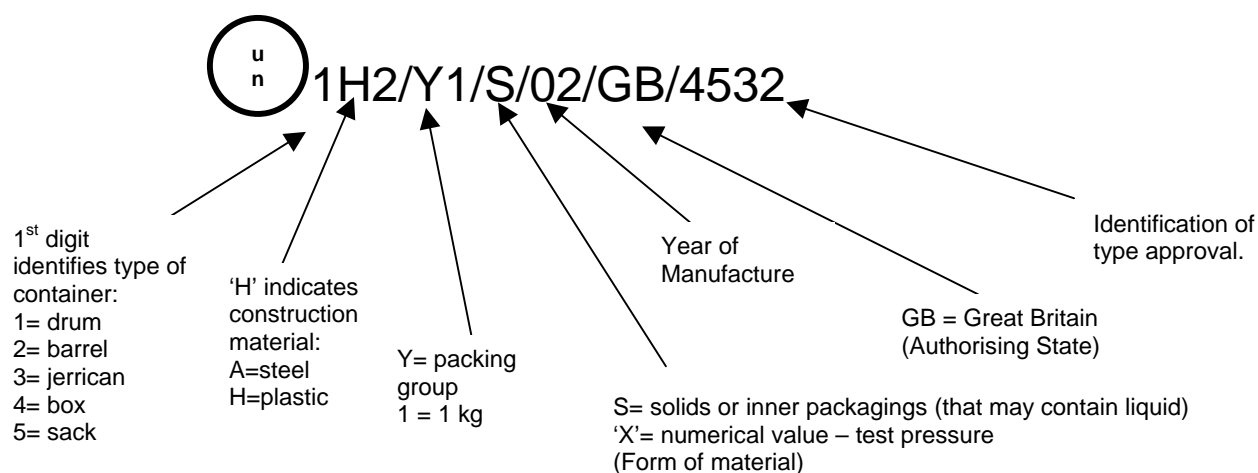
With regard to healthcare waste the following packaging groups are used:

Infectious Waste	Packing Group II (all infectious wastes)
Medicinal Waste	Packing Group II Packing Group III

8.12 Packing Instructions and Compliant Packaging

Section 4.1.4 of ADR specifies the packing instructions for all dangerous goods. The packing instructions specify the type and construction of the receptacle that the goods (including waste) may be carried in.

Dangerous goods should, (unless covered by a limited quantity exemption), be carried in approved compliant packaging. Compliant packaging is 'type approved' for a particular packaging group and should bear the appropriate mark to identify this. Section 6.1 of ADR specifies the marking requirements. An example mark is shown below:



Particular attention should be paid to the section of the code which specifies the form of the material to be carried. Free liquids should not be placed in receptacles designed for solids. It should be noted that many sharps boxes available on the market are type approved for solids only and should not be used for the disposal of liquid.

The following packing instructions are used for diagnostic specimens and healthcare waste

Dangerous Good	Packing Instruction	Example
UN2814 (Infectious Waste) (Group A)	P620	3-part rigid container
UN 3291 (Infectious Waste) (Group B) * See text overleaf	P621 IBC620 LP621	Sharps bin Wheelie bin (with sack)
Diagnostic Specimens	P650	Specimen pack
UN1851 (medicinal wastes)	P001	Box

UN3248	LP01 (not UN3248)	
UN3249	R001	Metal barrel

*Soiled Surgical Instruments and Dirty Linen

With the merger of Trusts and the centralisation of their services, a number of Trusts are now carrying used surgical instruments by road to a centralised sterile services facility. Such instruments, dependent upon an assessment of infection risk, should normally be classified as UN3291 (clinical waste). Occasionally a classification of UN2814 (infectious substance - where contamination is known/ suspected from pathogens of risk groups 2-4, e.g. hepatitis, HIV, CJD) would be more appropriate. However, as there is presently no 'UN type approved' rigid container under UN 2814, large enough or suitable for the carriage of instruments it is recommended that they be classified and packaged as UN3291.

The majority of used linen being transported to off-site laundries will not normally be assessed as dangerous for transport. There will be some occasional circumstances where soiled laundry will need to be classified as dangerous for transport, such as when a consignment is thought to contain pathogens which pose a significant risk of spreading disease, and the load is heavily soiled to the extent that the potential for exposure and infection is high. In such instances the load should then be classified and packaged as UN3291.

8.13 Special Packing Provisions

Special packing provisions apply to certain materials, they specify additional packing instructions. With regard to medicinal wastes, section 4.1.4 of ADR specifies that medicinal products (including waste) may be carried in packages no greater than 5 litres unless in limited quantities.

8.14 Limited Quantities

Section 3.4.6 of ADR specifies the limited quantity exemptions for certain types of dangerous goods. **There are no limited quantity exemptions for infectious waste.** Limited quantity exemptions apply to all medicinal wastes with the exception of flammable, toxic liquid medicines. The limited quantity exemption specifies the limit (volume/mass) of each package that may be carried in non-compliant packaging. It is recommended that advice is sought from a DGSA with regard to this. It should be noted that there is an exemption within the Carriage Regulations for medicinal products destined for retail and household use. However, it is not appropriate to use this exemption for waste.

8.2 Labelling

Section 5.2.1 of ADR specifies the labelling requirements for all dangerous goods packaging. In summary, all packages must be labelled with the UN Number of the material to be carried and the appropriate class mark (the nine classes of dangerous goods and their class marks are shown in Appendix B).

9.0 Storage

Healthcare waste containers may need to be stored before being transported to treatment/disposal sites. They should not be allowed to accumulate in corridors, wards or other places accessible to members of the public.

9.1 Storage at Point of Production

Storage areas at ward level should be secure and located away from public areas. Storage areas should be sufficient in size to allow packaged wastes to be segregated. It is not good practice to store wastes of different classifications together.

9.2 Bulk Storage

Bulk storage areas may be situated within healthcare premises, or at a licensed or permitted transfer or treatment/disposal facility.

Regardless of location, bulk storage areas should be:

- Reserved for healthcare waste only;
- Well lit and ventilated;
- Close to any on-site incineration or other disposal facility;
- Sited away from food preparation and general storage areas, and from routes used by the public;
- Totally enclosed and secure;
- Provided with separate storage for sharps containers, which may need a higher degree of security to prevent unauthorised access;
- Sited on a well-drained, impervious hard-standing;
- Readily accessible but only to authorised people;
- Kept locked when not in use;
- Secure from entry by animals and free from insect or rodent infestations;
- Provided with wash-down facilities;
- Provided with washing facilities for employees;
- Clearly marked with warning signs;
- Provided with separate, clearly labelled areas for waste destined for different treatment/disposal options;
- Provided with access to first aid facilities.

Size of Bulk Storage Areas

All bulk stores should have storage capacity to match the proposed frequency of collection. Bank or other holidays need to be taken into account, and a margin provided for any interruption in the disposal system.

Refrigerated Storage

Refrigerated storage may be required in hot weather if the waste poses a statutory nuisance, due to odour. If refrigeration is required, refrigerated storage units must be fitted with a device for opening from inside as a precaution against people being trapped.

Licences and Permits

A waste management licence or pollution prevention control permit may be required for the bulk storage of waste, even at the site of production. Reference should be made to section 12 of this guidance document for further information.

10.0 Transport

10.1 Internal Transport

Dedicated trucks, trolleys, tugs or wheeled containers are needed to transport waste containers to storage areas. In order to prevent contamination they should not be used for any other purpose. They need to be designed and constructed so that they:

- Are easy to clean and drain;
- Contain any leakage from damaged receptacles or containers;
- Are easy to load and unload;
- Do not offer harbourage for insects or vermin; and
- Do not allow particles of waste to become trapped on edges or crevices.

Containers for on-site transport need to be steam cleaned or disinfected following leakages or spills, and at regular intervals. If containers are heavily used, cleaning is likely to be required at least weekly. The healthcare waste procedures need to specify the method and frequency of steam cleaning or disinfection.

Internal vehicles should not be used to transport waste materials on the public highway.

10.2 External Transport

Dedicated vehicles must be used for the transport of healthcare waste on the public highways or on private roads accessed by the public. All drivers must receive training in the management of healthcare waste and be aware of the hazards and risks posed. If drivers are responsible for vehicles transporting clinical waste in excess of 333kg they require an ADR training certificate. Suitable personal protection equipment should be available to drivers and all vehicles should carry a spillage kit.

10.21 Special Provisions for Carriage

Section 7.3.3 of ADR specifies the special provisions for carriage. There is a special provision for the carriage of certain infectious waste classified as: V V 11.

V V 11 permits the carriage of these wastes in bulk (sacks) in specially equipped vehicles.

10.22 ADR Transport Categories

Section 1.1.3.6 of ADR specifies the transport categories used to determine the load thresholds over which the full provisions of ADR apply. The full requirements of ADR are onerous and include vocational ADR driver training and placarding of vehicles. The full provisions of ADR can be avoided if the total load carried does not exceed the load threshold. The load threshold for infectious waste in packages and medicinal waste is 333kg. Therefore, the full provisions of ADR do not apply to vehicles carrying less than 333kg

The load thresholds only apply to waste in packages, in accordance with the packaging instructions. Therefore, if waste is carried in bulk, for example, the carriage of hazardous infectious waste in sacks (see section 10.21), the full provisions apply immediately regardless of load or vehicle size.

Particular attention should be paid to the carriage of small quantities of waste in vehicles, e.g. community nursing, etc. If a bag of waste is placed directly into any vehicle, including a car, the vehicle and driver must comply with the full provisions of ADR. It is recommended that community practitioners review the types of packaging used and where possible avoid the use of sacks alone.

11.0 Treatment and Disposal

Clinical waste may be treated and disposed of in a number of different ways.

Treatment and disposal systems can be segregated into two broad types:

- Alternative;
- High Temperature.

Treatment and disposal methods need to be reliable and consistently achieve the claimed standard of treatment. Their performance needs to be measurable, and the process controlled precisely enough to reproduce the target standard.

Managers of waste treatment and disposal plants need to work to audited procedures. Procedures need to take into account the risks to operators as well as other people on the site, as well as the need to maintain standards of waste treatment.

All treatment and disposal systems which accept hazardous waste require a waste management licence or permit, this includes the treatment of waste at the point of production. All treatment and disposal facilities which accept waste on site for treatment or disposal require a waste management licence, a valid exemption or permit to operate. Waste management licensing is discussed in more detail in section 12.

All treatment or disposal facilities, regardless of size or type of technology used are required to 'render safe' the waste.

11.1 Rendered Safe

Rendered safe is defined as:

An accepted method or process has been applied which:

- (i) Reduces the apparent numbers or activity of pathogens so that no additional precautions are needed to protect workers or the public against infection by the waste
- (ii) Destroys any human tissue, organ or body part so that it is ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing, or breaking such that it is no longer generally recognisable
- (iii) Renders any syringes, needles or equipment unusable and no longer in their original shape and form

Note: these definitions, and the following criteria, do not apply to the treatment by laboratory autoclave, on the site of production of the waste, of microbiologically contaminated waste from a containment level 1-3 laboratory AND where suitable alternative controls are in place.

From January 1st 2006, alternative treatment plants should achieve the three criteria detailed below in order to demonstrate that the waste is 'rendered safe'. These criteria apply to:

- All non-incineration technologies that are used to treat clinical waste;
- Each individual device regardless of load capacity (<1kg to >100kg per hour) and permitting status;
- Existing operational devices as well as to devices being newly installed.

Where these have not been met the waste is not considered to have been rendered safe. This is applicable for the purposes of landfill, and further treatment would be required.

Criteria 1 Reduction in Pathogen Numbers

Microbial inactivation is a critical element of the 'rendering safe' of certain healthcare wastes. This guidance is based on the Level III criteria as the minimum required for clinical waste treatment as recommended by the State and Territorial Association on Alternative Treatment Technologies (STAATT).

STAATT Level III : inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 log₁₀ reduction or greater; and inactivation of *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores at a 4 log₁₀ inactivation or greater.

STAATT Level III : inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and mycobacteria at a 6 log₁₀ reduction or greater; and inactivation of *Geobacillus stearothermophilus* or *Bacillus atrophaeus* spores at a 4 log₁₀ inactivation or greater.

Criteria 2 Destruction of Anatomical Waste

Anatomical waste must be incinerated.

Alternative treatments are not appropriate for the treatment of this waste.

Criteria 3 Unusable and Unrecognisable

This criteria applies to all non-incineration technologies.

All hazardous and non-hazardous healthcare wastes processed through alternative treatment plants must be macerated rendering it unusable and unrecognisable.

11.11 The Rendering Safe of Pharmaceuticals and Chemicals within the waste

All pharmaceutically active substances, both hazardous and non-hazardous, should be destroyed during treatment. Healthcare wastes containing pharmaceutically active substances and chemicals should be disposed of in suitably authorised facilities, this will normally be by incineration.

11.2 Alternative Treatment

Alternative treatment is the name used to describe a broad range of waste management treatments that operate at temperatures less than 1000°C. There are three broad types of alternative technology:

- Heat;
- Chemical; and
- Irradiation.

Pre or integral maceration of the waste is a requirement of 'rendered safe'.

11.21 Heat Treatment

Thermal systems use heat to inactivate pathogenic micro-organisms and, in those that utilise high temperatures, simultaneously destroy the waste. Most pathogens are rapidly inactivated at 60 to 80°C.

Autoclaves

Autoclaves or steam sterilisation have been used for over a century as a means of treating specific forms of waste, such as infected samples from pathology departments. Saturated steam is introduced into a vessel, forcing out the air in the chamber by its heavier mass

(gravity displacement or gravity autoclave) or the steam is pulled into the vessel after the air has been exhausted by a vacuum system (vacuum displacement or vacuum autoclave). As the steam accumulates, the pressure and temperature within the chamber increase until the minimum temperature/pressure requirements for the treatment process have been met.

These conditions are then maintained to render the waste sterile. At the conclusion of the exposure period, the steam is slowly exhausted from the chamber until the pressure falls to one atmosphere. It is the combination of temperature, pressure and time which inactivates pathogens. The use of 'challenge loads' and/or thermocouples may be used to verify the treatment process. Some autoclaves are specifically designed to shred the waste during the treatment cycle, other systems rely on the use of a pre-treatment process to macerate the waste before the waste is heated. The use of internal paddles/arms/ridges designed to mix waste inside the autoclave chamber may not meet the requirements for maceration.

Steam Auger

This industrial steam sterilisation process operates at ambient pressure using a combination of residence time and temperature to treat the waste and render it safe. Waste is shredded prior to its entry into a steam auger where it is turned and treated with steam until the minimum requirements for treatment have been met.

Dry Heat

Some waste treatment systems available for both large (e.g. hospitals) and small quantity generators (e.g. GPs/dentists) thermally inactivate potentially pathogenic micro-organisms through the use of electrically generated heated air, oil, or molten plastic. A number of commercial facilities in the UK use a hot-oil process.

Microwaves

Microwaves are electromagnetic waves with a frequency between radio waves and infrared waves on the electromagnetic scale. When applied to the treatment of waste, the mechanism of microbial inactivation is thermal. It is important for the waste to be wet, either as a result of moisture naturally occurring in the waste stream or by the addition of moisture in the form of steam. The combination of the two, microwaves and moisture, create the thermal process. Some treatment processes utilise microwaves to heat water to form steam which is then applied to the clinical waste stream. "Dry" microwave systems are also available. This uses direct microwave energy in a nitrogen atmosphere to treat the waste and produces higher treatment temperatures than those used by "wet" microwave technologies.

11.22 Chemical

Chemicals have an extensive and well documented history in the clinical setting in disinfecting environmental surfaces and medical devices. Chemicals commonly used are sodium hypochlorite, chlorine dioxide, peracetic acid, glutaraldehyde and quaternary ammonium compounds. The waste must first be shredded in order to bring all surfaces of the waste into direct contact with the chemicals. Some systems combine heat with the chemicals to reduce the treatment cycle.

11.23 Irradiation

Gamma irradiation (e.g. Cobalt-60) has been used for many years as a means of inactivating potential pathogens on the surfaces of many different medical products. Since the appropriate dose of radiation can be precisely calculated, it has been found to be an extremely reliable treatment system. A newer form of irradiation system employs an electron beam generated by an accelerator to sterilise medical products and, potentially, clinical waste. Irradiation systems require extensive shielding to protect the workers, can only treat relatively small quantities of waste and do not alter the physical appearance of the material.

11.3 High Temperature

High temperature technologies are often described collectively as incinerators and are regulated as incineration installations. When high temperature treatment such as pyrolysis, plasma technology or gasification is used, and one or more of the products is subsequently combusted (including the "producer gas"), then both the pyrolyser/gasifier/plasma process and the subsequent combustion process are considered to be incineration processes according to the Waste Incineration Regulations 2002.

Pyrolysis

Pyrolysis involves the high temperature (545 to 1000°C) combustion of waste in the absence of oxygen. In generating these high temperatures, the systems treat, destroy, and reduce the volume of clinical waste.

Plasma Technology

In a plasma system, an electric current is discharged through an inert gas (e.g. argon) to ionise it and in turn cause an electric arc to create temperatures as high as 6000°C. The clinical waste within the system is brought to temperatures between 1300 to 1700°C,

destroying potentially pathogenic microbes and converting the waste into a glassy rock or slag, ferrous metal, and inert gases.

Gasification

The process of gasification is similar to the process of controlled air incineration in that the waste materials are thermally decomposed, but in an oxygen starved (sub stoichiometric) atmosphere. The wastes in the gasification process are ignited and are reduced in a self-sustaining process. No support fuel is consumed save for that required to initiate combustion. The decomposition results in the generation of volatile gaseous material and, depending on the waste content, various vaporised tar oil fractions. The waste gas is passed through a series of scrubbers/filters and cyclonic separators to provide a clean "producer gas".

11.4 Discharge to Sewer

Any discharge to sewer, other than domestic sewage, must have the prior agreement of the statutory responsible bodies; that is the Environment Agency and sewerage undertaker in England and Wales. Anybody intending to dispose to sewer any waste which may present a substantially greater risk than domestic sewage should first seek advice.

Radioactive wastes from diagnosis and intensive radiotherapy have low radioactivity and short half lives. If the waste is a water-miscible fluid, and the discharge authorisation permits, it may be disposed of to sewer.

11.5 Specific Treatment/Disposal Requirements

11.51 TSE Infected Waste

Waste known or suspected to be contaminated with Transmissible Spongiform Encephalopathy (TSE) agents, including CJD must be disposed of by incineration in suitably authorised facilities.

Additional guidance on the management of TSE infected waste is available in: Transmissible Spongiform Encephalopathy: Safe Working and the Prevention of Infection, which is published on the DH website at :

http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CJD/CJDGeneralInformation/CJDGeneralArticle/fs/en?CONTENT_ID=4031067&chk=4gOe2r

11.52 Cytotoxic and Cytostatic Waste

Waste contaminated with cytotoxic and/or cytostatic substances should be disposed of in suitably authorised facilities, which will normally be incineration facilities.

Sharps boxes containing sharps contaminated with cytotoxic and/or cytostatic products should be disposed of in facilities authorised to accept cytotoxic and cytostatic waste only.

11.53 Waste Containing Genetically Modified Organisms (GMOs)

The Genetically Modified Organisms (Contained Use) Regulations 2000 require that waste contaminated with GMOs or Genetically Modified Micro-organisms (GMMs) be inactivated by a validated means.

"Inactivation" is defined as the *"complete or partial destruction of GMOs so as to ensure that any contact between the GMos and humans or the environment is limited to an extent commensurate with the risks identified in the risk assessment and to provide a high level of protection for humans and the environment"*. This implies that the degree of inactivation required will vary depending on the nature of the organisms being used.

There are a number of commercial treatment/disposal facilities currently used for infectious waste that are able to effectively inactivate GMO waste. However, inactivation of contaminated waste by these facilities does not obviate the requirement to have an autoclave on site/ in the building/ in the laboratory suite (depending on the classification of the organisms involved). There is a clear distinction as to where the inactivation needs to take place, depending on the GMO risk class of the waste:

- **Class 1** - Waste may be transported for off-site inactivation by validated means;
- **Class 2** - Waste to be inactivation within building prior to off-site treatment/disposal;
- **Class 3** - Waste to be inactivated within the laboratory suite; prior to off-site treatment/disposal;
- **Class 4** - Waste to be inactivated within the laboratory suite; prior to off-site treatment/disposal;

It should be noted that there are implications where Class 2 GMO activity waste is also classified infectious waste falling within Category B (in Carriage Regulation). Infectious wastes classified in Category B are routinely transported off-site for treatment or disposal.

However, in accordance with The Genetically Modified Organisms (Contained Use) Regulations 2000, such waste must be inactivated on site prior to off-site treatment/disposal

Contractors who collect waste for treatment/disposal containing GMOs before it has been inactivated are subject to the requirements of the Contained Use Regulations. For example, contractors may collect waste in sealed containers which they then incinerate or otherwise treat to ensure inactivation. The contractor in this case is undertaking a contained use activity, namely destruction of the GMOs and must register as a GM centre with the Competent Authority. Guidance on the activity notification (registration) is available from the HSE.

Where the GMO waste has been treated to inactivate it prior to collection by a waste contractor the contractor is not undertaking a contained use activity. The waste may be collected and treated or disposed of without the need to consider the Contained Use Regulations

Further guidance on the inactivation and disposal of GMO and GMM waste can be obtained from the HSE.

11.54 Mercury

The disposal of mercury is subject to specific control. Depending on the circumstances the Trade Effluent (Prescribed Processes and Substances) Regulations 1989, the Water Industry Act 1991 and the Water Resources Act 1991 might apply to the discharge and release of mercury to the environment. Mercury should not normally be discharged to the sewer. Any discharge to the sewer requires consent from the Sewerage Undertaker. Dental amalgam is generally recovered by separators or sieves, and should be sent for appropriate recovery and disposal.

11.56 Radioactive waste

Radioactive wastes must be disposed of only under the terms of an authorisation granted by the environmental regulatory agencies (Environment Agency) under the Radioactive Substances Act 1993 or under an exemption under that Act. Those disposing of such waste should seek the advice of the Radiation Protection Adviser appointed under the Ionising Radiations Regulations 1985 both as regards the protection of staff and permitted means of disposal.

12.0 Waste Management Licensing and Permitting

EU policy on waste management is that Member States should promote:

- Waste reduction and prevention;
- The use of cleaner technologies;
- Reusable/recyclable products;
- Energy recovery;
- Reduction of disposal of waste to landfills; and
- An integrated network of waste management facilities.

This should be achieved without danger to human health or the environment. As a consequence, most waste management activities, ranging from a small transfer station, through to recycling facilities, composting and landfilling, to incineration, require some form of authorisation under legislation which aims to prevent environmental pollution or harm to human health.

The regulatory instruments that are most commonly applied to healthcare waste management are Waste Management Licensing and PPC Permitting, these are considered in this section. However, other legislation may also be applicable and it should be borne in mind that different aspects of a proposed operation may be regulated by different regulatory instruments. Regulatory controls often run in parallel with, and overlap, the planning process. Application for a permit or licence to operate a facility and an application for planning permission should not be considered in isolation.

12.1 Relationship with Planning Permission

The majority of waste management activities require planning permission to have been granted for the proposed development before a PPC Permit or Waste Management Licence can be issued, although a permit can be issued for certain activities (including incineration) in advance of a planning permission. The planning process considers the principles of land use and whether a change of use is acceptable in a local or even regional context, the effect that the proposed development is likely to have on the local environment and the amenities of residents living in the vicinity. Permission is then granted subject to conditions designed to ensure that the development does not have a detrimental effect upon the locality. Whether Planning Permission is granted for a development is determined by a committee formed from the elected members of the local authority. This can result in delays and appeals against decisions, resulting in increased costs and delays in providing necessary waste management facilities.

12.2 Pollution Prevention Control (PPC) Permits

Activities subject to control by 'Permit' under The Pollution Prevention and Control (PPC) Regulations 2000 are listed in Chapter 5 of Schedule 1 to the Regulations, and include:

- Disposal of Waste by Incineration (Sect. 5.1);
- Disposal of Waste by Landfill (Sect. 5.2);
- Disposal of Waste Other than by Incineration or Landfill (Sect. 5.3);
- Recovery of Waste. (Sect. 5.4);
- The Production of Fuel from Waste (Sect. 5.5).

A PPC permit is generally required to operate large facilities or those involved in the management of hazardous waste or a considerable amount of general waste, for example, a permit is required when:

- Greater than 50 tonnes of non-hazardous waste are treated (or sorted) per day;
- Greater than 10 tonnes of hazardous waste are treated (or sorted) per day.

Applications for a PPC permits should be made to the Environment Agency. PPC applications require a significant amount of information; the applicant must consider all the environmental impacts associated with the installation. Once submitted a copy of the application will be placed on a public register, held in the local office of the Environment Agency, which the public is free to view. Once the consultation period is over the Agency considers all the representations received and will either grant the permit subject to conditions or reject the application. If an operator is dissatisfied with a decision made regarding an application, an appeal to the Secretary of State can be made. Information and guidance on applying for a PPC permit is available from the DEFRA and EA web sites.

If a permit is granted, the Agency must ensure that the following general principles are adhered to;

- All appropriate preventative measures are taken against pollution, in particular through application of Best Available Techniques;
- No significant pollution is caused;
- Waste production is avoided and where waste is produced, it is recovered. Where that is not possible it is disposed of in a way producing the least impact on the environment, if any impact is produced at all;
- Energy is used efficiently;
- Measures are taken to avoid accidents and limit their consequences;
- Necessary measures are taken on the closure of an installation to avoid any pollution risk and return the site to a satisfactory condition.

The Pollution Prevention and Control Act 1999 introduced Best Available Techniques (BAT) assessment into waste management control. Applications are required to demonstrate that that there proposed installation is 'BAT'.

Best Available Techniques:

- **Best** means the most effective techniques for achieving a high level of protection for the environment as a whole.
- **Available** techniques means techniques developed on a scale which allows them to be used in the relevant industrial sector, under economically and technically viable conditions taking account of the cost and the advantages. The techniques don't have to be used or produced in the United Kingdom as long as they are reasonably accessible; and
- **Techniques** includes both technology and the way the installation is designed, built, maintained, operated and decommissioned.

12.21 The Waste Incineration Regulations 2003

The Waste Incineration Regulations 2003 implement the provisions of Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste. The Regulations require the operators of certain existing waste incineration installations (within a specified period) to apply for a permit under the PPC Regulations or the Environmental Protection Act 1990 providing the information specified. The Regulations prohibit certain waste incineration installations or mobile plants from being put into operation until the relevant application has been determined, although there are transitional provisions for waste incineration installations or mobile plants which will now require a permit under The Pollution Prevention and Control (PPC) Regulations 2000.

12.3 Waste Management Licences

The Waste Management Licensing Regulations 1994 provide a system of conditional authorisation with the objective of ensuring that the storage, treatment or disposal of waste does not cause pollution of the environment, harm to human health or serious detriment to local amenities.

A waste management licence is required for all activities which involve the storage, treatment or disposal of waste. A licence is not generally required to store waste on the site of production however, there are limits to the quantities that may be stored without a licence.

Applications for a waste management licence should be made to the Environment Agency. Generally, the information requirements for a waste management licence are less onerous than for a PPC permit. Information and guidance on applying for a waste management licence is available from the DEFRA and EA web sites.

Licence applicants are required to demonstrate that they are “fit and proper” persons, comprising technical competence, financial security and to declare any relevant convictions.

A 'fit and proper', person is one who is:

- Technically qualified to operate a facility of the type proposed,
- Has no 'relevant' convictions,
- Is able to make financial provision to meet the requirements of the permit, including long term maintenance and monitoring of the facility.

The Waste Management Licensing Regulations 1994 (as amended) provide exclusions and exemptions from waste management licensing under Regulations 16 and 17 and Schedule 3. Exclusions from waste management licensing are provided for waste recovery or disposal operations where pollution prevention or harm to human health is fully dealt with or by other legislative controls. Exemptions from waste management licensing are mainly for small-scale waste storage and waste recovery operations and are subject to certain limitations. These limitations are general rules under which the waste activity can take place and cover such details as the types and quantities of waste permitted, the methods of disposal or recovery, and pollution control measures.

12.31 Examples of Healthcare Related Exemptions

Schedule 3 of the Waste Management Licensing Regulations 1994 (as amended) contains details of exemptions from the requirement for a waste management licence in accordance with Regulation 17 and 18 of the 1994 regulations..

The table overleaf provides some details of exemptions which may be applicable in the Healthcare waste sector.

Exempt activities under Waste Management Licensing Regulations

Schedule 3 Para No	Activity exempt	Register with Agency	Hazardous waste included	Maximum quantity	Storage time	Comments
39(1)	Storage of returned medicines	Yes	Yes	5 m ³	6 months	Applies to pharmacies receiving returned medicines from households or individuals
39(2)	Storage of medical practice waste	Yes	Yes	5 m ³	3 months	<p>Medical practice waste includes waste returned by patients or from patient visits. If the maximum amount is exceeded the practice must apply to Environment Agency for a licence.</p> <p>Covers the storage of waste at ambulance stations that has been produced from patient care off-site, so long as this was not at another ambulance station.</p> <p>Covers the storage of returned waste on the premises of general medical, dental and veterinary practices so long as this did not arise from another such practice. Covers waste returned by domestic properties and residential care homes.</p> <p>This exemption does not apply to:</p> <ul style="list-style-type: none"> ◆ Denaturing of controlled drugs. ◆ Storage of returned waste other than medicines, e.g. diabetic sharps. ◆ Storage of waste from organisations or institutions, for example care homes providing nursing care.

40	Off-site storage of non-liquid waste	No	No	50 m ³	3 months	Applies to off-site storage in areas not designed or adapted to receive waste. The storage must be incidental to the collection and transport of the waste. Although not requiring regulator consent it does require the owner/occupier's consent. Covers the transfer of non-hazardous waste from an ambulance to an A&E department so long as Duty of Care requirements are met and storage arrangements are considered suitable under the regulations.
41	On-site temporary storage of hazardous waste	No	Yes	80 m ³ in secure containers 50 m ³ in secure place 23,000 litres for liquid waste	12 months	Applies to waste awaiting collection on the site where it was produced. Covers the storage of waste produced on the premises of hospitals, care homes providing nursing care, general medical, dental and veterinary practices and ambulance stations. <u>Note</u> – care homes providing nursing care may have to notify the Environment Agency that they are a hazardous waste producer before such waste is removed from the site for disposal.
22	Recovery of silver from printing or photographic waste	No	No	50,000 litres per day	NA	Also permits the storage of printing or photographic waste awaiting processing. Potentially exempts the operation of silver reprocessing unit associated with X-ray activities so long as the associated materials (e.g. fixer/developer) are not considered hazardous waste.
11	Preparatory treatment of certain wastes	No	No	100 – 3,000 tonnes per week depending on waste type	NA	Applies to activities performed with a view to the recovery or reuse of the waste. Includes activities such as baling, sorting and shredding of waste paper, cardboard, plastic and textiles and the sorting, crushing or washing of glass.

In general activities relating to healthcare waste that are not encompassed by these exemption will need a waste management license or other form of permit

Small Clinical Waste Treatment Plant (On-Site)

There is no exemption for the small scale treatment of clinical waste. Recent evidence of inadequate treatment require that stringent controls are applied to any alternative treatment device regardless of scale.

12.4 Waste Management Licence and Permit Conditions

Conditions attached to a permit or licence will impose controls upon the development and operation of the facility which are designed to ensure that no significant pollution is caused, setting out clearly the standards to be achieved and imposing emission limit values for pollutants. Failure to comply with these conditions is an offence and may lead to the facility having its licence/permit revoked, the operators being fined (up to £20,000) or even imprisoned.

Licence and permit conditions can be modified or varied, usually by amending conditions or changing the Working Plan. They can also be suspended or revoked, in part or whole.

12.5 Compliance Monitoring

Both licences and permits are issued subject to conditions designed to ensure that the operation of the facility does not cause pollution or endanger health. The Environment Agency will inspect a facility periodically to ensure that it is being operated in accordance with these conditions. If the conditions are not producing the desired result, or if the operator needs to change their method of operation in some way, the conditions can be modified. If this does not produce the necessary result, then the licence or permit can be revoked or suspended. The frequency of inspection, the nature and required detail of observations and the length of time taken by an inspection will depend upon the type and size of licensed facility and whether it is subject to any requirement for more intensive inspection; persistent non-compliance with licence conditions or concern over recent monitoring results.

13.0 Documentation

13.1 Transport Documentation

The Carriage Regulations require that a completed transport document should accompany all loads of dangerous goods, with the exception of goods being transported under limited quantity exemptions. The format and content of the transport document are specified in section 5.4 of ADR. In summary the transport document should provide the following information:

1. The UN Number of the goods being carried;
2. The proper shipping name, supplemented where applicable with the technical name;
3. The label model number;
4. The packaging group;
5. The number and description of the packages;
6. The total quantity of each item;
7. The name and address of the consignor;
8. The name and address of the consignees;

In addition to a transport document those transporting dangerous goods above the load thresholds stated in section 1.1.3 of ADR are required to carry instructions in writing as a precaution against accident or emergency during carriage. These written instructions are commonly referred to as a TREMCARD. Section 5.4.3 of ADR provides further details.

13.2 Waste Transfer Note

A key element of the duty of care is keeping track of the waste. The holder of the waste is responsible for:

- taking adequate steps to ensure that the waste is managed safely, and kept secure; and
- transferring it only to an authorised or exempt person

When waste is transferred from one party to another, the person handing it on (the "transferor") must complete a transfer note. The transferor and the recipient (the "transferee") sign the note; both of them take and keep a copy of it. An Annual Transfer Note may be used to cover all the movements of regular consignments of the same waste, between the same parties

A transfer note must state:-

1. The quantity of waste transferred, by weight where possible.
2. How it is packed
3. Type of container
4. A description of the waste

The description of the waste should include:

- (a) The European Waste Catalogue code, as indicated elsewhere in this guidance
- (b) The type of premises or business from which the waste comes.
- (c) The name of the substance or substances
- (d) The process that produced the waste
- (e) A chemical and physical analysis
- (f) Special problems identified under (i) to (xi) below

The description must provide enough information to enable subsequent holders to avoid mismanaging the waste.

Special problems:

- (i) Any special containment requirements
- (ii) Type of container required, and material the container is made of
- (iii) Can it be safely mixed with other wastes, or are there wastes with which it should not be mixed.
- (iv) Can it be safely crushed and transferred from one vehicle to another
- (v) Can it be safely incinerated or does it require specific minimum temperatures or combustion times
- (vi) Can it be disposed of safely to landfill with other waste
- (vii) Is it likely to change physical state during storage or transport
- (viii) Any information, advice or instructions about the handling, recovery or disposal of the waste by the waste regulators, or suppliers etc.
- (ix) Details of problems previously encountered with the waste
- (x) Changes to the description since the previous load
- (xi) Anything unusual about the waste that may pose a problem.

It is good practice to label drums and containers with the description of the waste.

Copies of transfer notes should be retained by all parties for a minimum of 2 years

13.21 Dual Transfer/Transport Notes

The information contained on a waste transfer note is very similar to the waste required for the transport note. It is common practice to combine these notes, this can be done by providing an adequate description of the waste and any hazardous characteristics using both waste and carriage terminology.

13.3 Consignment of Hazardous Waste

Producers of hazardous waste are required to notify premises at which they produce hazardous waste.

It is an offence not to notify premises at which hazardous waste is produced (unless they are exempt premises) or to remove hazardous waste from premises, which are not notified (or exempt from notification). Exempt premises are listed in regulation 23(3) of the Hazardous Waste (England and Wales) Regulations 2005 and include:

- 23(3) (f) premises used by a dental, veterinary or medical practice, to the extent that the premises are used for that purpose.

The Regulations also state that premises are exempt:

- if less than 200kg (in total) of hazardous waste is produced in any twelve months period; and
- the waste is removed by a registered carrier (under the Control of Pollution (Amendment) Act 1989) or a person exempt from registration.

This means that the premises described in regulation 23(3) are only exempt providing the qualifying limitation of less than 200kg hazardous waste in any twelve month period is met and the waste is removed by a registered carrier or person exempt from registration.

If the quantity of hazardous waste exceeds 200kg in any twelve month period, the exemption afforded to medical practices no longer applies, and relying on it may put the practice at risk. This is particularly important as monitoring of waste quantities at most practices is not precise enough to know accurate waste quantities at any one time. It will therefore be very difficult to know exactly when, and if, the limit of 200kg per year is reached.

13.31 Producer Notification

The Notification Process involves providing certain information to the Environment Agency, via an 'Application for Registration as a Hazardous Waste Producer', including:

- The number of employees (within a range)
- Your Standard Industrial Classification Code (SIC 2003) (what activities are carried out on your site)
- Companies House registration number (if you are Ltd or Plc)
- A valid e-mail address.

Applications for Registration can be made by Internet, Phone or by Post. Full instructions, including a help line number, how to pay by credit/debit card and other information such as interim measures on how to deal with Consignment Notes during the determination of your application, are detailed on the following page of the Environment Agency's website:

<http://www.environment-agency.gov.uk/subjects/waste/1019330/1029396>

All sites producing hazardous waste, with the exception of exempt premises, are required to notify the Environment Agency, including healthcare centres, GP practices, etc. Notification can be made by a central body (e.g. the Trust) but each site requires a separate notification. Guidance on the notification procedure for multi-occupancy sites is available from the Environment Agency web site.

Following notification the Environment Agency will provide each notified with a unique Notification reference. This reference must be used on Hazardous Waste Consignment Notes. Guidance on the use of the notification reference and requirements for exempt premises can be found on the Environment Agency web site.

13.32 Consignment Notes

The layout and content of a Hazardous Waste Consignment Note is specified the Hazardous Waste Regulations 2005. Waste producers may produce their own consignment, may use consignment notes supplied by a waste contractor or may use an Environment Agency note. Printed blank consignment notes are available from the Environment Agency for a small charge, alternatively a blank note can be downloaded from the Environment Agency web site.

13.4 Registered Waste Carriers

A Waste Carrier is someone whose business or part of their business involves the transporting of controlled waste by road, rail, air, sea or inland waterways. The following carriers are exempt from registration under the Controlled Waste (Registration of Carriers and Seizure of Vehicles) Regulations:

- Householders who carry only household waste, generated by them, in their own vehicle
- Waste producers carrying their own waste, except building or demolition waste.
- Holders of a knacker's yard licence or a licence under the Animal By-Products Order.
- people such as community nurses and others working in home healthcare;
- healthcare providers' vehicles carrying waste generated by them

Waste Carriers are required to register with the relevant environmental regulator (Environment Agency) and comply with the Duty of Care. All registrations last for 3 years from the date of issue or renewal. Registered carriers should be able to provide a certificate of registration on request.

14.0 Accidents and Incidents

Employers at all points in the waste chain need written procedures for dealing with accidents or incidents including spillages. These procedures should form part of the waste management policy and should include:

- Immediate first-aid measures. In the case of sharps injuries, procedures need also to cover arrangements for suitable medical advice and counselling;
- Immediate reporting to a responsible designated person;
- Recording of the accident/incident;
- Investigation of the incident, and implementation of remedial action. Initial investigation should preferably take place before any damaged container is removed;
- Retention, if possible, of the item and information about its source to help identify possible infection risks;
- Attendance of any injured person at an accident and emergency department or occupational health department as soon as possible;
- Involvement of the risk manager;
- Involvement of the waste manager;
- Involvement of the Infection Control Team.

All incidents involving spillages, damaged packaging, inappropriate segregation or any incident involving sharps need to be reported to the line manager or other suitable individual, and investigated by them. The investigation of these accidents and incidents needs to establish the cause, and what action needs be taken to prevent a recurrence.

The analysis and investigation of incidents involving healthcare waste, whether reportable or not, helps identify causes, trends, the level of compliance with current legislation, the effectiveness of the precautions in place, and problem areas for which satisfactory precautions have yet to be provided. Information relating to both the financial cost and staffing required to deal with incidents is also relevant as it allows managers to assess the total cost of incidents and accidents. The depth of each investigation will vary, depending on the nature of the incident. To be worthwhile, however, any investigation needs to consider carefully the underlying causes. Action after an accident will not be effective if it addresses only the superficial and obvious causes, and misses more significant issues.

The active and reactive monitoring of clinical waste procedures is most effective as part of an overall system of health and safety monitoring, with information passing up the line management chain to senior management.

14.1 RIDDOR

Certain major injuries, all injuries resulting in an employee being unable to carry out their normal duties for more than 3 days and specified occupational diseases, including infections reliably attributable to the work activity, and specified dangerous occurrences such as an accident or incident that results in, or could have resulted in, the release of a biological agent that could cause severe human disease are reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). Severe human disease includes diseases caused by Hazard Group (HG) 3 and 4 agents, as well as some HG2 agents e.g. *Neisseria meningitides*. All RIDDOR reports should be made to the appropriate enforcing authority, for most healthcare premises, this is the Health and Safety Executive. Records of these incidents must be kept. Social Security legislation requires an accident book or something similar to be kept and accessible to staff. Effective health and safety management systems ensure the internal reporting, recording and investigation of a wider range of accidents and incidents than those which are legally reportable.

14.2 Spillages

Employers need clear written procedures for dealing with spillages which:

- Specify the reporting and investigation procedures;
- Specify the use of a safe system of work for clearing up the healthcare waste;
- Set out appropriate requirements for decontamination;
- Specify the protective clothing to be worn.

The ready availability of appropriate spillage kits helps ensure the correct action in the event of a spillage. Such kits are particularly useful at storage, waste treatment and waste disposal sites and should be carried on all vehicles carrying healthcare waste.

Spillage kits may contain, for example:

- Disposable gloves;
- A disposable apron;
- A infectious waste sack/medicinal waste container;

- Paper towels;
- Disposable cloths;
- Disinfectant recommended, for example, by the local control of infection policy;
- A means of collecting sharps.

Employers need to provide appropriate equipment for collecting spilled waste and placing it in new containers. Sharps must not be picked up by hand. Spilled waste and any absorbent materials need to be placed in a infectious waste container for disposal.

14.21 Disinfectants

The use of suitable disinfectants should be detailed in the healthcare waste policy. The policy should clearly identify which disinfectants should be used where and for what purpose. The policy should also provide guidance on the relevant level of dilution required and the contact time required for the disinfectant to be effective. Disinfectants containing 10 000 ppm available chlorine are recommended for spillages. The use of sodium dichloroisocyanurate (NaDCC) granules is also generally recommended, as prepared solutions lose activity with time and require regular replacement. Suitable inert, absorbent materials may also be used to deal with liquid spillages after disinfectant material has been applied. Guidance on the use of disinfectants should be sought from suitably qualified personnel for example, infection control team. They should be consulted after a spillage containing or suspected to contain unusual infective agents, for example variant CJD. Recent guidance on the use of disinfectants in cases of known or suspected CJD infection recommends the use of 20 000 ppm sodium hypochlorite (NaOCl) or 1M sodium hydroxide (NaOH) with contact time of one hour.

The use of disinfectants themselves may present a health risk, particularly in confined spaces and consideration should be given to the general provisions of the COSHH Regulations.

14.22 Mercury

Employers who use mercury should carry out a risk assessment for dealing with mercury spillages, and produce written procedures . A spillage kit including disposable plastic gloves, paper towels, a bulb aspirator for the collection of large drops of mercury, a vapour mask, a suitable container fitted with a seal and mercury absorbent paste (equal parts of calcium hydroxide, flowers of sulphur and water) needs to be available. In no circumstances should a vacuum cleaner or aspiration unit be used, as this will vent mercury vapour into the atmosphere.

15.0 Personal Protection & Hygiene

15.1 PPE

The Personal Protective Equipment at Work Regulations 1992 state that employers must not use personal protection as the first line of defence against health risks, unless all other reasonably practical precautions have been taken. Risk assessments should identify situations in which the hazard cannot be adequately controlled by any other means and personal protective equipment is required. In such cases, employers must ensure that these items are provided, used and maintained. They must also make appropriate arrangements for storage and cleaning. Under the law employees must co-operate with employers to ensure that their legal duties are met.

A risk assessment of the work done by staff who regularly handle, transfer, transport, treat or dispose of infectious waste is likely to show that they require:

- Suitable heavy duty gloves when handling clinical waste containers;
- Safety shoes or industrial wellington boots to protect the feet against the risk of containers being accidentally dropped. The soles of such shoes or boots may also need to provide protection against the spillage of sharps and slippery floors;
- An industrial apron or leg protectors if container handling creates a risk of bodily contact.

Protective face visors, helmets and strong industrial gloves are needed where incinerators or other machines are charged manually.

COSHH assessments should be used to identify circumstances where respiratory protection is required.

For situations such as cleaning spillages, the risk assessment may indicate a need for protective equipment to prevent skin contact. In these cases, disposable gloves and aprons are best. In some circumstances, face visors may be necessary to protect employees from splashing. Such instances should be identified in local procedures.

15.2 Basic hygiene

Basic personal hygiene is important in reducing the risk from handling healthcare waste. Employers need to ensure that washing facilities are convenient for people handling healthcare waste; this is particularly important at storage and incineration facilities.

15.3 Immunisation

Staff handling clinical waste should be offered appropriate immunisation, including Hepatitis B and tetanus. Staff must be informed of the benefits (e.g. protection against serious illness, protection against spreading illness) and drawbacks (e.g. reactions to the vaccine) of vaccination. Where vaccination has been identified as a control measure required when working with clinical waste the employer must offer this free of charge. Employers need to establish arrangements for dealing with staff who decline to accept the immunisation services that are offered and those who do not sero-convert.

16.0 Training and Competence

A policy for the safe management of healthcare wastes cannot be effective unless it is applied carefully, consistently and universally. This requires that all hospital personnel should be aware of the policy/procedure and that it is implemented by trained and competent people.

16.1 Training

Training needs vary depending on the responsibilities and job function. Ideally, separate training programmes should be designed for, and targeted on, the following groups:

- Hospital managers and administrative staff responsible for implementing regulations on clinical waste management;
- Medical doctors;
- All nursing and infection control staff; and
- Cleaners, porters, auxiliary staff and waste handlers.

Those delivering training should have experience in teaching and training and be familiar with the risks and practices of clinical waste management. Smaller establishments generating healthcare waste may not have this range of expertise available to them, but should still have access to competent advice on clinical waste issues.

16.2 Training Procedures

Training procedures and information need to:

- Be written in a way which can be understood by those who need to follow them, including those who may not have a good command of English;
- Take account of different levels of training, knowledge and experience;
- Be up to date;
- Be available to all staff including part time, shift, temporary, agency and contract staff;
- Be available in all areas.

Managers need to ensure that procedures are followed by all staff. Staff at all levels who generate the waste need to recognise that they are personally responsible for complying with agreed local procedures.

16.21 Training Records

The risk assessments required by the Management Regulations and COSHH should identify which staff are involved in handling of healthcare waste. Under the Health and Safety at Work etc. Act 1974, the Management Regulations, and COSHH they must receive information on:

- The risks to their health and safety i.e. the details of the substances hazardous to health to which they are likely to be exposed
- The significant findings of the risk assessment;
- Any precautions necessary;
- The results of any monitoring carried out; and
- The collective results of any relevant health surveillance.

A training record will readily enable line managers to identify members of staff who are not receiving the appropriate level of training, and where such training should be focused.

16.22 Induction Training

Training needs vary depending on the job and on the individual. All staff involved in handling healthcare waste need training, information and instruction in:

- The risks associated with healthcare waste, its segregation, handling, storage and collection;
- Personal hygiene;
- Any procedures which apply to their particular type of work;
- Procedures for dealing with spillages and accidents;
- Emergency procedures; and
- The appropriate use of protective clothing.

Training for staff who collect, transfer, transport or handle quantities of healthcare waste needs to cover:

- Checking that storage containers are sealed effectively before handling;
- Ensuring that the origin of the waste is marked on the container;
- Handling sacks/containers correctly
- Using handles to move rigid containers;

- Checking that the seal on any used waste storage container is unbroken when movement is complete;
- Special problems relating to sharps disposal;
- Procedures in case of accidental spillage and how to report an incident;
- Safe and appropriate cleaning and disinfection procedures.

16.23 Job Specific Training

Some staff require more specific training; these include people who use protective equipment, incinerator operators, drivers, community and laboratory staff. Under the Environmental Protection Act 1990 (section 74), operators of waste management facilities require a certificate of competence from the Waste Management Industry Training and Advisory Board (WAMITAB). Drivers of vehicles used to transport healthcare waste by road may need additional training under the Carriage Regulations and those responsible for the movement of the waste should have access to, or be a trained Dangerous Goods Safety Advisor (DGSA)

16.24 Delivery of Training

Training can be delivered in a variety of ways depending on the audience, this may include workshops and formal seminars for senior staff and hands-on training in the workplace for smaller groups. The training can serve to educate staff and should include for each group:

- Information on, and justification for, all aspects of clinical waste policy;
- Information on the role and responsibilities of each hospital staff member in implementing the policy; and
- Technical instructions, relevant for the target group, on the application of waste management practices.

16.25 Assessment

Testing the applicants at the end of the training programme is a useful way of gauging the uptake of knowledge although some form of vocational assessment in the workplace, post completion and periodically thereafter, is often more accurate in assessing the transfer of knowledge, skills and understanding. This also provides an opportunity to update knowledge in line with policy or procedural changes.

17 Conclusion

We would welcome responses to the questions:

- Do you agree with the recommendation that clinical waste is redefined as hazardous infectious waste? If not, please give explanations?
- Do you agree with the methodology proposed of identifying and classifying infectious and medicinal waste? If not, identify what alternative approach or methodology would be more acceptable?
- Do you agree with the benefits of introducing an “offensive waste” stream?
- Do you agree with the benefits of a nationally based system of colour-coded packaging? If not, please suggest any recommendations for an alternative approach?

We would welcome views on:

- the practicality of segregating sharps waste contaminated with cytotoxic/cytostatic medicinal products and sharps boxes not contaminated with cyto-medications. Suggestions are sought as to how waste products can demonstrate effective waste segregation.

Comments and other responses should be sent by post, fax or e-mail to:

John Prendergast
Project Editor, Publications
Central Office of Information (COI)
1st Floor east
City House
New station St.
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LS1 4JG

Fax: 0113 283 6586

E-mail: SMHCW@coi.gsi.gov.uk

Comments and other responses should reach the Department of Health no later than 7 February 2006.

17.1 Confidentiality Disclaimer

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances; this will mean that your personal data will not be disclosed to third parties.

17.2 Cabinet Office Code of Practice on Consultations

This consultation is carried out in the context of the following criteria contained in the *Cabinet Office Code of Practice on Consultation*:

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.
2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses
3. Ensure that your consultation is clear, concise and widely accessible
4. Give feedback regarding the responses received and how the consultation process influenced the policy
5. Monitor your department's effectiveness at consultation, including through the use of a designated consultation coordinator
6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment, if appropriate

Respondents are invited to comment on the extent to which the criteria have been adhered to and to suggest ways for further improving the consultation process. Comments or complaints about the consultation process, **but not your response to the consultation itself**, should be directed to:

Steve Wells

Consultations Co-ordinator

Department of Health

Skipton House

80 London Road

London

SE1 6LH

E-mail: steve.wells@dh.gsi.gov.uk

Safe management of healthcare waste

Response Form

PERSONAL DETAILS

Title	Mr / Mrs / Ms / Dr / Professor / Other
First Name(s)	
Surname	
Address	
Post Code	
E-mail Address	

IF YOU ARE REPLYING ON BEHALF OF A GROUP OR ORGANISATION

Name of Organisation	
Address (if different from above)	
Post Code	
E-mail Address	

Please insert 'X' if you want us to keep your response confidential

Do you agree with the recommendation that clinical waste is redefined as hazardous infectious waste? If not, please give explanations? (Section 4.15)

Comments

Q: Do you agree with the methodology proposed of identifying and classifying infectious and medicinal waste? If not, identify what alternative approach or methodology would be more acceptable? (Section 5.0)

Comments

Do you agree with the benefits of introducing an “offensive waste” stream? (Section 5.3)

Comments

Do you agree with the benefits of a nationally based system of colour-coded packaging? If not, please suggest any recommendations for an alternative approach? (Section 7.1)

Comments

Views are sought on the practicality of segregating sharps waste contaminated with cytotoxic/cytostatic medicinal products and sharps boxes not contaminated with cyto-medications. Suggestions are sought as to how waste products can demonstrate effective waste segregation. (Section 7.2)

Comments

Do you have any other general comments you would like to make?

Comments

Please return (to arrive no later than 7 February 2006) by post, fax or e-mail to:

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Further Information & References

Regulations and Approved Codes Of Practice

Health and Safety at Work etc Act 1974 SI 1974/1439 The Stationery Office 1974 ISBN 011 141439 X

Management of Health and Safety at Work Regulations (MHSWR) 1999 SI 1999/3242 The Stationery Office 2000 ISBN 011 0856252 2

A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 L73 (Second edition) HSE Books 1999 ISBN 07176 2431 5

Control of Substances Hazardous to Health Regulations (COSHH) 2002 SI 2002/2677 The Stationery Office 2002 ISBN 011 042919 2

The Control of Substances Hazardous to Health Regulations 2002. (as amended). Approved Code of Practice and Guidance L5 (Fifth edition) HSE Books 2005 ISBN 07176 2981 3

Electricity at Work Regulations 1989 SI 1989/635 The Stationery Office 1989 ISBN 011 096635 X

Workplace health, safety and welfare. Workplace (Health, Safety and Welfare) Regulations 1992. Approved Code of Practice L24 HSE Books 1992 ISBN 07176 0413 6

Management of health and safety at work. Management of Health and Safety at Work Regulations 1999. Approved Code of Practice and guidance L21 (Second edition) HSE Books 2000 ISBN 07176 2488 9

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995: Guidance for employers in the healthcare sector Health Services Information Sheet HSIS1 HSE Books 1998

HSE Guidance

Management of health and safety in the health services: Information for directors and managers HSE Books 1994 ISBN 07176 0844 1 O/P

Five steps to risk assessment Leaflet INDG163(rev1) HSE Books 1998 ISBN 07176 1565 0

Safety representatives and safety committees. Approved Code of Practice and Guidance on the Regulations L87 (Third edition) HSE Books 1996 ISBN 07176 1220 1

A guide to the Health and Safety (Consultation with Employees) Regulations 1996. Guidance on Regulations L95 HSE Books 1996 ISBN 07176 1234 1

Occupational exposure limits: Containing the list of maximum exposure limits and occupational exposure standards for use with the Control of Substances Hazardous to Health Regulations 1999 Environmental Hygiene Guidance Note EH40 HSE Books 2002 Supplied with Occupational exposure limits: Supplement 2003 Environmental Hygiene Guidance Note EH40/2002 HSE Books 2003 ISBN 07176 2194 4

Latex and you Leaflet INDG320 HSE Books 2000

Manual handling. Manual Handling Operations Regulations 1992. Guidance on Regulations L23 (Second edition) HSE Books 1998 ISBN 07176 2415 3

Safe working and the prevention of infection in clinical laboratories and similar facilities HSE Books 2002 ISBN 07176 2513 3

Manual handling in the health services HSE Books 1998 ISBN 07176 1248 1

Health surveillance at work HSG61 (Second edition) HSE Books 1999 ISBN 07176 1705 X

Glutaraldehyde and You IACL64(rev1) HSE Books 1998

Successful health and safety management HSG65 (Second edition) HSE Books 1997 ISBN 07176 1276 7

New and expectant mothers at work: A guide for employers HSG122 HSE Books 1994 ISBN 07176 0826 3

Infection risks to new and expectant mothers in the workplace: A guide for employers HSE Books 1997 ISBN 07176 1360 7

Reducing noise at work. Guidance on the Noise at Work Regulations 1989 L108 HSE Books 1998 ISBN 07176 1511 1

HSE Guidance notes for the protection of persons against ionising radiation arising from medical and dental use National Radiological Protection Board 1998 ISBN 085951 286 X Tel: 01235 822742

Consulting employees on health and safety: A guide to the law Leaflet INDG232 HSE Books 1996 ISBN 07176 1615 0

Biological Agents: Managing the risks in laboratories and healthcare premises. HSE Books May 2005.

Advisory Committee on Dangerous Pathogens (ACDP) Guidance

Biological agents: managing the risks in laboratories and healthcare premises (<http://www.hse.gov.uk/biosafety/biologagents.pdf>)

Infection at work: controlling the risks (<http://www.hse.gov.uk/pubns/infection.pdf>)

Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection

(http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/CJD/CJDGeneralInformation/CJDGeneralArticle/fs/en?CONTENT_ID=4031067&chk=4gOe2r)

Infection at Work: Controlling the Risks, produced by the by the Advisory Committee on Dangerous Pathogens and published on Health and Safety Executive (HSE) website

NHS/Department of Health Guidance

Guidance for clinical health care workers: protection against infection with blood-borne viruses UK Health Departments/Department of Health

Chemical disinfection in hospitals Health Protection Agency 1993 Website: www.hpa.org.uk

Latex sensitisation in the health care setting (use of latex gloves) DB9601 Medical Devices Agency 1996 Tel: 020 7972 8000

Information to undertakers: infectious diseases 1988 PL/CMO(88)7 Department of Health 1988

Decontamination of equipment prior to inspection, service and repair Health Service Guidelines HSG(93)26 Department of Health

Controls assurance in infection control: decontamination of medical devices Health Service Circular HSC1999/179 NHS Executive/Department of Health

Washer-disinfectors: Design considerations Health Technical Memorandum 2030 Department of Health

Sterilisation Health Technical Memorandum 2010 Department of Health

Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission Health Service Circular HSC 1999/178 NHS Executive/Department of Health

The management of health, safety and welfare issues for NHS staff HSC (98)064 Department of Health

Joint Committee on Vaccination and Immunisation (see paragraph 137) against infectious disease The Stationery Office 1996 ISBN 011 321815 X Department of Health/The Stationery Office

Hepatitis B infected health care workers HSC2000/020 Department of Health

HIV Post-Exposure Prophylaxis: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS UK Health Departments 2000 Department of Health

British Standards

BS 7320:1990 Specification for sharps containers British Standards Institution ISBN 05801 8481 1

BS 2745-1: 1993 Washer-disinfectors for medical purposes. Specification for general requirements British Standards Institution ISBN 05802 1570 9

BS 2745-2: 1993 Washer-disinfectors for medical purposes. Specification for human waste container washer-disinfectors British Standards Institution ISBN 05802 2015 X

BS 2745-2: 1993 Washer-disinfectors for medical purposes. Specification for washer-disinfectors except those used for processing human-waste containers and laundry British Standards Institution ISBN 05802 2154 8

Other

Middlemiss D Health and Safety: Funeral Services Staff Handbook Funeral Standards Council 1988 O/P

The Management of Health, Safety & Welfare Issues for NHS Staff, NHS Employers Organisation 2005.

http://www.nhsemployers.org/KeepingInTouch/occupational_health_guidance.asp#hwp

Appendix A European Waste Catalogue

European Waste Catalogue Chapters

Chapter Number	Production sector/Origin of Waste
Chapter 1	Wastes from exploration, mining and quarrying, physical and chemical treatment of minerals
Chapter 2	Waste from agriculture, horticulture. Aquaculture, forestry, hunting and fishing, food preparation and processing.
Chapter 3	Wastes from wood processing and the production of panels and furniture, pulp, paper and cardboard.
Chapter 4	Wastes from the leather, fur and textile industries.
Chapter 5	Wastes from petroleum refining, natural gas purification and pyrolytic treatment of coal
Chapter 6	Waste from inorganic chemical processes.
Chapter 7	Waste from organic chemical processes.
Chapter 8	Wastes from the manufacture, formulation, supply and use of coatings (paints, varnishes and vitreous enamels), adhesives, sealants and printing inks.
Chapter 9	Wastes from the photographic industry.
Chapter 10	Wastes from thermal processes.
Chapter 11	Wastes from chemical surface treatment and coating of metals and other materials, non-ferrous hydrometallurgy.







Chapter 12




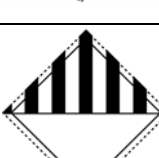
Wastes from shaping and physical and mechanical surface treatment of metals and plastics.

Chapter Number	Production sector/Origin of Waste
Chapter 13	Oil wastes and wastes of liquid fuels.
Chapter 14	Waste organic solvents, refrigerants and propellants.
Chapter 15	Waste packaging, absorbents, wiping cloths, filter materials and protective clothing not otherwise specified.
Chapter 16	End of life vehicles from different means of transport and vehicle maintenance.
Chapter 17	Construction and demolition wastes.
Chapter 18	Waste from human or animal healthcare and/or related research.
Chapter 19	Wastes from waste management facilities, off-site waste water treatment plants and the preparation of water intended for human consumption and water for industrial use.
Chapter 20	Municipal waste (household waste and other similar commercial, industrial and institutional wastes (including separately collected fractions)).

Appendix B Carriage Information

The table below shows the 9 Classes of dangerous goods. Examples are given of dangerous goods in each class that may be generated from healthcare and the appropriate hazard warning diamond for the primary hazard is also shown

UN Hazard Classification		Examples material from health care premises.	Hazard Warning Diamond(s)
Class 1	Explosives		 1.4
Class 2	Gases	Oxygen, CO2, LPG, Nitrous Oxide and Nitrogen	 2 (red diamond used for flammable gases)
Class 3	Flammable liquids	Fuel for generators, Surgical disinfectants and 'scrubs', Paints and Sealants	 3
Class 4	Flammable solids and other flammables, including water reactive substances		 4
Class 5	Oxidizers	Laundry chemicals and strong detergents	 5.2
Class 6	Toxic substances (poisonous by absorption, ingestion or inhalation) Class 6.1	Some medicines.	 6
Class 6	Infectious substances (substances known or	Laboratory cultures. Infectious waste.	

	reasonably expected to contain infectious pathogens) Class 6.2		 <p>INFECTIONIOUS SUBSTANCES In case of damage or leakage immediately notify public health authority 6</p>
Class 7	Radioactive	Radio-therapy isotopes	 <p>RADIOACTIVE III Contains radioactivity 7</p>
Class 8	Corrosive substances	Strong bleaches and Chemical de-scalers	 <p>CORROSIVE 8</p>
Class 9	Miscellaneous	Laundry additives	 <p>9</p>

The table below shows the ADR2005 Category A Pathogen List.

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A	
IN ANY FORM UNLESS OTHERWISE INDICATED (ADR 2005. Section 2.6.3.2.2.1 (a))	
UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substances affecting humans	<i>Bacillus anthracis (cultures only)</i> <i>Brucella abortus (cultures only)</i> <i>Brucella melitensis (cultures only)</i> <i>Brucella suis (cultures only)</i> <i>Burkholderia mallei - Pseudomonas mallei – Glanders (cultures only)</i> <i>Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)</i> <i>Chlamydia psittaci - avian strains (cultures only)</i> <i>Clostridium botulinum (cultures only)</i> <i>Coccidioides immitis (cultures only)</i> <i>Coxiella burnetii (cultures only)</i> Crimean-Congo hemorrhagic fever virus Dengue virus (cultures only) Eastern equine encephalitis virus (cultures only) <i>Escherichia coli, verotoxigenic (cultures only)</i> Ebola virus Flexal virus <i>Francisella tularensis (cultures only)</i> Guanarito virus Hantaan virus Hantaviruses causing hantavirus pulmonary syndrome Hendra virus Hepatitis B virus (cultures only) Herpes B virus (cultures only) Human immunodeficiency virus (cultures only) Highly pathogenic avian influenza virus (cultures only) Japanese Encephalitis virus (cultures only) Junin virus Kyasanur Forest disease virus

	<p>Lassa virus Machupo virus Marburg virus Monkeypox virus</p> <p><i>Mycobacterium tuberculosis (cultures only)</i> Nipah virus Omsk hemorrhagic fever virus Poliovirus (cultures only) Rabies virus <i>Rickettsia prowazekii (cultures only)</i> <i>Rickettsia rickettsii (cultures only)</i> Rift Valley fever virus Russian spring-summer encephalitis virus (cultures only) Sabia virus <i>Shigella dysenteriae type 1 (cultures only)</i> Tick-borne encephalitis virus (cultures only) Variola virus Venezuelan equine encephalitis virus West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis (cultures only)</i></p>
<p style="text-align: center;">UN 2900 Infectious substances affecting animals only</p>	<p>African horse sickness virus African swine fever virus Avian paramyxovirus Type 1 - Newcastle disease virus Bluetongue virus Classical swine fever virus Foot and mouth disease virus Lumpy skin disease virus <i>Mycoplasma mycoides</i> - Contagious bovine pleuropneumonia Peste des petits ruminants virus Rinderpest virus Sheep-pox virus Goatpox virus Swine vesicular disease virus Vesicular stomatitis virus</p>

Appendix C Classification of Medicinal Wastes

All medicinal wastes displaying the hazardous properties:

- H6 (toxic),
- H7 (carcinogenic),
- H10 (toxic for reproduction) and
- H11 (mutagenic)

above the thresholds described in the Joint Agencies Hazardous Waste guidance (WM2) should be classified as cytotoxic and cytostatic waste.

The table below shows a list of cytotoxic and cytostatic medicines. It should be noted that this list is provided as a guide and is not comprehensive. Further guidance should be sought from the dispensing pharmacist.

Drug Name	Commercial Name
Aldesleukin	Proleukin
Alemtuzumab	MabCampath
Alitretinoin	
Atretamine	
Amsacrine	Amsidine
Anastrozole	Arimidex
Arsenic trioxide	
Asparaginase	
Azacitidine	
Azathioprine	Imuran
Bacillus Calmette-Guerin	ImmuCyst; OncoTICE
Bexarotene	Targretin
Bicalutamide	Casodex
Bleomycin	Bleomycin
Busulfan	Busilvex; Myleran
Capecitabine	Xeloda
Carboplatin	Paraplatin; Carboplatin
Carmustine	BiCNU; Gliadel
Cetrorelix acetate	
Chlorambucil	Leukeran
Chloramphenicol	Kemicetine; Chloramphenicol
Choriogonadotrophin alfa	Ovitrelle
Cidofovir	Vistide
Cisplatin	Cisplatin
Cladribine	Leustat

Colchicine	Colchicine
Cyclophosphamide	Endoxana; Cyclophosphamide
Cytarabine	DepoCyte; Cytarabine
Cyclosporin	Neoral; Sandimmun
Dacarbazine	DTIC-Dome; Dacarbazine
Dactinomycin	Cosmegen Lyovac
Daunorubicin HCl	DaunoXome; Daunorubicin
Denileukin	
Dienestrol	
Diethylstilbestrol	Diethylstilbestrol
Dinoprostone	Propess; Prostin E2
Docataxel	Taxotere
Doxorubicin Hydrochloride	Caelyx
Dutasteride	Avodart
Epirubicin Hydrochloride	Pharmorubicin
Ergonovine/methylethergonovine	
Estradiol	Numerous
Estramustine phosphate	Estracyt
Oestrogen-progesterone combinations	Several
Oestrogens	Several
Estrone	Hormonin
Estropipate	Harmogen
Etoposide	Etoposide; Etopophos; Vepesid
Exemestane	Aromasin
Finasteride	Proscar
Floxuridine	
Fludarabine	Fludara
Fluorouracil	Fluorouracil; Efudix
Fluoxymesterone	
Flutamide	Flutamide; Drogenil
Fulvestrant	Faslodex
Ganciclovir	Cymevene
Ganirelix	Orgalutran
Gemcitabine	Gemzar
Gemtuzumab ozogamicin	
Gonadotrophin Chorionic	Choragon; Pregnyl
Goserelin	Zoladex; Zoladex LA
Hydroxycarbamide	Hydrea
Ibritumomab tiuxetan	
Idarubicin	Zavedos
Ifosfamide	Mitoxana
Imatinib mesylate	Glivec
Interferon alfa	
Irinotecan HCl	Campto
Leflunomide	Arava
	Femara

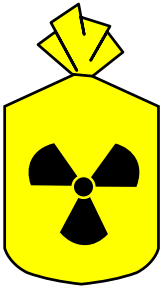
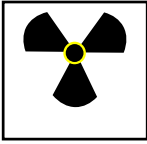
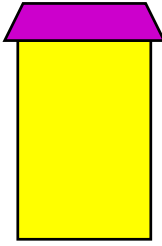
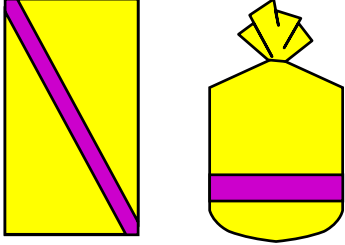
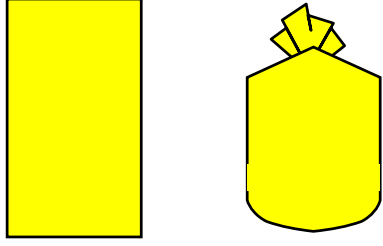
Letrozole	Lomustine
Leuprolide acetate	Megace
Lomustine	Alkeran
Mechlorethamine	Menogon; Menopur
Megestrol	Puri-Nethol
Melphalan	Methotrexate
Menotropins	Mifegyne
Mercaptopurine	Mitomycin C Kyowa®
Methotrexate	Onkotrone; Novantrone;
Methyltestosterone	CellCept
Mifepristone	Synarel
Mitomycin	Eloxatin
Mitotane	Syntocinon; With ergometrine
Mitoxantrone	Taxol
Mycophenolate mofetil	Pentacarinat
Nafarelin	Nipent
Nilutamide	Posalfilin
Oxaliplatin	Procarbazine
Oxytocin	Crinone; Cyclogest; Gestone
Paclitaxel	Various
Pegaspargase	Evista
Pentamidine isetionate	Tomudex
Pentostatin	Copegus; Rebetol; Virazole
Perphosphamide	Prograf
Pipobroman	Tamoxifen; Nolvadex
Piritrexim isethionate	Temodal
Plicamycin	Various
Podofilox	Thalidomide
Podophyllum resin	Lanvis
Prednimustine	Thiotepa
Procarbazine	Hycamtin
Progesterone	
Progestins	
Raloxifene	
Raltitrexed	
Ribavrin	
Streptozocin	
Tacrolimus	
Tamoxifen	
Temozolomide	
Teniposide	
Testolactone	
Testosterone	
Thalidomide	
Tioguanine	
Thiotepa	


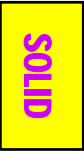
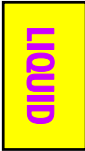
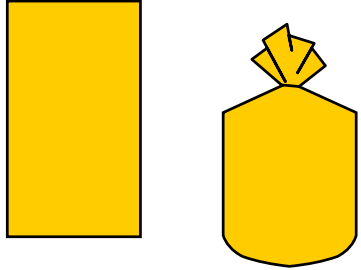
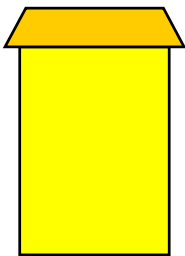

Topotecan	Fareston
Toremifene citrate	
Tositumomab	Vesanoid
Tretinoin	
Trifluridine	
Trimetrexate glucuronate	Triptorelin
Triptorelin	
Uracil mustard	Valcyte
Valganciclovir	
Valrubicin	
Vidaradine	Vinblastine; Velbe
Vinblastine sulphate	Vincristine; Oncovin
Vincristine sulphate	Elsidine
Vindesine	Navelbine
Vinorelbine tartrate	Retrovir; +abacavir & lamivudine
Zidovudine	

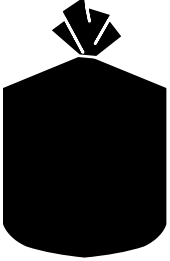
Cytotoxic and cytostatic waste should be incinerated in suitable licensed facilities. The following description of cytotoxic and cytostatic waste should be used on waste documentation:

“Waste pharmaceuticals including cytotoxic and cytostatic medicines”

Appendix D Waste Segregation Chart

Waste Receptacle	Example Contents	EWC Code(s)	Hazardous Properties	Primary Transport Class	UN Number(s)	Minimum Treatment / Disposal Required
	Healthcare waste contained with radioactive material	18 01 03 if waste is infectious	H9 if waste is infectious Radioactive	Class 6.2 (Infectious) + Class 7 (Radioactive)	UN 3291 + UN Number will depend on isotope* <small>*Seek guidance from DGSA</small>	Hazardous waste incineration with suitable authorisation for radioactive materials (Subject to RSA 1993)
	Non – infectious radioactive waste including radio-pharmaceuticals	NA	'H' Code not applicable. Radioactive	Class 7 (Radioactive)	UN Number will depend on isotope* <small>*Seek guidance from DGSA</small>	Hazardous waste incineration with suitable authorisation for radioactive materials (Subject to RSA 1993)
	Sharps contaminated with cyto-toxic and /or cyto-static medicinal products	18 01 01 18 01 03 18 01 08	H6 H7 H9 H10 H11	Class 6.2 (Infectious)	UN 3291	Hazardous waste incineration
	Infectious waste contaminated with cyto-toxic and /or cyto-static medicinal products	18 01 03 18 01 08	H6 H7 H9 H10 H11	Class 6.2 (Infectious)	UN 3291	Hazardous waste incineration
	Infectious waste requiring incineration including anatomical waste.	18 01 02 18 01 03	H9	Class 6.2	UN 3291	Hazardous waste incineration

	Amalgam waste	18 01 10	H6	NA	NA	Recovery
Waste Receptacle	Example Contents	EWC Code(s)	Hazardous Properties	Primary Transport Class	UN Number(s)	Minimum Treatment / Disposal Required
 	Residual medicines NOT in original packaging	18 01 08 18 01 09	H6 H7 H10 H11	Class 6.1	UN 3248 UN 1851 UN3249	Hazardous waste incineration
	Infectious and potentially infectious waste. Treated laboratory waste	18 01 03	H9	Class 6.2	UN 3291	Licensed / permitted treatment facility
	Sharps not contaminated with cyto products	18 01 01 18 01 03	H9	Class 6.2	UN 3291	Licensed / permitted treatment facility
	Offensive Waste Human hygiene waste. Non-infectious disposable equipment, bedding and plaster casts	18 01 04 or 20 01 99*	NA	NA	NA	Landfill
* human hygiene waste from non-healthcare sources.						

	<p>Domestic Waste</p> <p>General refuse, including newspapers, flowers, etc.</p>	<p>20 03 01</p>	<p>NA</p>	<p>NA</p>	<p>NA</p>	<p>Landfill</p>
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Appendix E Example Documentation

NOT AVAILBLE FOR CONSULTATION

Sector Guides

NOT AVAILABLE FOR CONSULTATION

We will gratefully invite contributions from the following individual sector groups with regard to the management of waste generated within their own sphere of activity and taking into account any specific issues brought about by new and proposed legislative requirements:

- Primary Care
- Ambulance Service
- Community Nursing
- Care Homes
- General Practitioners
- Dental Practitioners
- Home Treatment
- Veterinary Surgeons
- Pharmacy
- Needle Exchange
- Acupuncturists
- Funeral Directors
- Research Establishments & Laboratory Facilities
- Schools & Offices
- Local Authority
- Day Care and Nurseries