

Guidance for Disposal and Recycling of Medical Devices

1. Objective

- 1.1 The objective of this guidance is to advise NHS Boards and contractors on how to dispose of recycle used medical devices.

This guidance has been produced for all those who are responsible for the management of single-use and reusable medical devices when the devices are no longer required.

2. Scope and Definitions

Scope

- 2.1 The scope of this document is recycling of reusable and single use medical devices for metal recovery.

Medical Device

- 2.2 A medical device as defined by European Council Directive [93/42/EEC](#) amended 2007¹ is “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Reusable Medical device

- 2.3 Reusable medical devices are devices that can be reprocessed for subsequent patient use.

Single Use

- 2.4 A device designated as ‘single-use’ must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient².



Figure 1: Symbol used to denote single use device.

3. Classification of Discarded Medical Devices

- 3.1 Discarded (used and unused) devices are classified as healthcare (clinical) waste. Comprehensive guidance on the management of waste is provided in [Scottish Health Technical Note 3 \(SHTN3³\)](#), available from the HFS web site (www.hfs.scot.nhs.uk).

European Waste Catalogue (EWC) and Written Description

- 3.2 Environmental Regulation requires waste producers to adequately describe their waste using both a written description and by indicating the appropriate European Waste Catalogue (EWC)⁴ code(s).

Discarded medical devices are classified using the same **EWC code** 18 01 03 as other potentially infectious healthcare wastes:

18 01 03	wastes whose collection and disposal are subject to special requirements in order to prevent infection
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Table: 1 Extract from the EWC catalogue

The written description should provide sufficient information to alert personnel in the waste management chain how the material should be handled.

Special Waste

- 3.3 Healthcare waste that poses a risk of infection (**EWC 18 01 03**)⁴ is classified as a special waste.

The [Special Waste Amendment \(Scotland\) Regulations 2004⁵](#) define and regulate the segregation and movement of special waste in Scotland from the point of production to the final point of disposal or recovery. The Regulations require producers of special (hazardous) waste to complete consignment notes and notify Scottish Environment Protection Agency (SEPA), prior to the movement of the waste off-site.

Guidance on the consignment of special waste is available from the SEPA web site. http://www.sepa.org.uk/waste/waste_regulation/special_waste.aspx

Prior to the movement of healthcare waste off-site, a consignment note must be completed. The note should contain details of the amount of waste, the **EWC** code and the written description. NHS Boards already consign special waste from their premises, and further guidance should be sought from the NHS Board’s Waste Management Officer. Where the same contractor collects other healthcare wastes from the site, different types of waste may be collected separately necessitating separate consignment notes.

4. Segregation and packaging of discarded medical devices

Segregation

- 4.1 Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing.

Once discarded (used or unused) medical devices are considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must be recorded, handled and stored in accordance to [SHPN 13 Series 2^{6,7,&8}](#) and [SHTN 3³](#) and in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.

Where a recycling service is to be used, the advice of the waste contractor should be sought regarding specific requirements for container type and labelling requirements of the used instrument recycling stream.

Packaging

- 4.2 Discarded devices should be placed in UN type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner. Guidance on the type and colour of container should be sought from the Board Waste Management Officer.

NHS Scotland has developed a colour coding approach for healthcare waste containers which reflects regulatory and contractual requirements. The colour-coded segregation system identifies and segregates waste on the basis of waste classification and suitability of treatment/disposal options. 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.

Waste which requires disposal by incineration

- 4.3 Yellow rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility. A list of licensed contractors can be obtained on the SEPA website or from the Waste Management Officer.

Waste which may be treated and recycled

- 4.4 Containers which comply with UN type P/LP621 and are provided by the waste contractor should be used. These containers will be uplifted by the contractor and may be treated offsite to reduce infection risk prior to recycling/disposal. Any material recovered will then be sent to a third party metal recycling facility. At the time of writing this guidance a number of trials were underway. Initial figures from one board involved in the trial for the year July 2013 to July 2014 are shown in [Appendix 1](#). The trials are being conducted using reusable rigid containers which are UN type approved for healthcare (clinical) waste. In addition the containers should be clearly labelled stating the type of medical devices



Figure 2: Container currently used in MD recycling trials.

5. Disposal and Recycling

When possible, recycling of waste material should be the preference as it is consistent with a zero waste approach. Recycling options should be considered at the time of procurement to ensure materials recovery is a viable option.

Healthcare waste, including used devices can only be treated or disposed of in facilities with the appropriate authorisations (waste management licences / permits), and reference should be made to European Waste Catalogue (EWC)⁴ codes for the type of waste accepted by the facility. However, the codes only make up part of the description of the waste and some waste management facilities capable of taking infectious waste (EWC 18 01 03)⁴ will not be authorised to take used medical devices (section 3.1).

At the current time in Scotland used medical devices are managed in three ways:

- Specialist clinical waste for incineration;
- Treatment (autoclave) at waste facility to render them safe e.g. remove the infectious risk, prior to sending for metal recycling;
- Disposal, treatment (autoclaves) at waste facility with no subsequent metal recycling.

CJD/vCJD Risk

Devices previously used in the treatment of patients with, or 'at increased risk of CJD or vCJD⁹ should be handled as agreed by The Advisory Committee on Dangerous Pathogens (ACDP). The "Transmissible Spongiform Encephalopathy (TSE) Working Group guidance 2003 amended 2014" states:

"The ACDP TSE Working Group considered the disposal of clinical waste, and have agreed that tissues, and contaminated materials such as dressings and sharps, from patients with, or "at increased risk" of, CJD/vCJD, should be disposed of as in the following table 2".

Diagnosis of CJD	High or medium risk tissue*	Low risk tissue and body fluids**
Definite	Incinerate	Normal clinical waste disposal
Probable	Incinerate	Normal clinical waste disposal
“At increased risk”	Incinerate	Normal clinical waste disposal

Table 2: Disposal of clinical waste from patients with, or “at increased risk” of, CJD or vCJD

* See Annex A1 of “The Transmissible Spongiform Encephalopathy (TSE) Working Group guidance 2003 amended 2014”.

** Tissues and materials deemed to be low risk include body fluids such as urine, saliva, sputum, blood, and faeces. Blood from vCJD patients is considered to be low risk except when transfused in large volumes.’

As most medical devices contain only small amounts of blood or tissue this waste would be considered low risk and so suitable for pre-treatment and disposal. Also when considering the disposal of quarantined medical devices in their 2011 annual report Annex M the [ACDP](#) stated that:

“Members were presented with two options for disposal of the instruments originally collected. Both proposed disposal routes were based on a limited body of evidence describing the destruction of infectivity by an incineration temperature of 1000°C for 15 minutes. Members agreed that either of the proposed options were satisfactory but emphasized the importance of ensuring an audit trail and that audit records on the incinerator (e.g. temperature logs) were kept.”

Currently, this can only be achieved in a limited number of waste treatment facilities although new treatment plants are under construction. Therefore there should be no reason why used medical devices cannot be sent for metal recovery as long as the above requirements are assured.

A Service Level Agreement (SLA) for recycling or disposal between the Board and contractor should be put in place. The SLA should include provision for the following as a minimum:

- Allocation of responsibility and duties;
- Collection frequency;
- Collection points;
- Costs and/reimbursements (incentives);
- Packaging and labelling;
- Handling and investigation of complaints;
- Tracking of waste until treated.

References

- 1. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.**
<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF>
- 2. Medicines and health regulatory Authority, Device Bulletin, Single-use Medical Devices: Implications and Consequences of Reuse.**
<http://www.mhra.gov.uk/home/groups/dts-iac/documents/publication/con2025021.pdf>
- 3. Health Facilities Scotland, Scottish Health Technical Note, SHTN 3 Waste Management Guidance. Health Facilities Scotland (2010).**
<http://www.hfs.scot.nhs.uk/online-services/publications/environment/shtns/>
- 4. Commission Decision of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.**
<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000D0532:20020101:EN:PDF>
- 5. The Scottish Government, The Special Waste Amendment (Scotland) Regulations 2004.** <http://www.legislation.gov.uk/ssi/2004/112/contents/made>
- 6. Health Facilities Scotland, Scottish Health Planning Note, SHPN 13 , Decontamination Facilities. Part 1 (2011)** <http://www.hfs.scot.nhs.uk/online-services/publications/decontamination/>
- 7. Health Facilities Scotland, Scottish Health Planning Note, SHPN 13 , Decontamination Facilities. Part 2 (2008)** <http://www.hfs.scot.nhs.uk/online-services/publications/decontamination/>
- 8. Health Facilities Scotland, Scottish Health Planning Note, SHPN 13 , Decontamination Facilities. Part 3 (2010)** <http://www.hfs.scot.nhs.uk/online-services/publications/decontamination/>
- 9. Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection: Part 4 (2014)**
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/270732/Part_4_Infection_control_of_CJD_vCJD_and_other_human_prion_diseases_in_healthcare_and_community_settings.pdf

Appendix 1

Table A1: Savings achieved from single use podiatry Instruments (SUI) diverted from landfill between July 2013 and July 2014.	
Number of re-usable Sharps containers serviced	3981
Total Weight of SUI recycled/Kg	22040
Tonnes of metal waste diverted from landfill (approximate)	22.00
Tonnes of plastic diverted from landfill (single use sharps bins)	4.30
Pay back to the Board per tonne	£42
Total saving from rebate	£1,104.60