SEPA Guidance

Export of Waste Medical Devices

Purpose

The purpose of this guidance is to inform medical practices (hospitals, health centres, clinics etc.) who may be considering exporting waste medical devices (e.g. cardiac catheters) overseas for recycling or for re-use.

Background

Waste medical devices contaminated with blood and other body fluids are classified as clinical waste due to the risk of infection and therefore fall into the category of special waste (or hazardous waste) (Typically classified under List of Waste code 18 01 03*).

The transport, treatment and disposal of waste within the United Kingdom and its export are subject to a range of regulatory controls. There are additional regulatory controls if the waste is classified as "special" or "hazardous" waste.

Medical Practices in Scotland should be aware of the following specific issues when considering exporting waste medical devices abroad for recycling or re-use.

- Is it Special waste?
- Treatment at the medical practice;
- Regulatory controls on the export of waste; and
- MHRA guidance on reuse of single-use Medical Devices.

Special Waste

The movement of this waste to destinations within the UK is subject to the Special Waste Regulations 1996 (as amended).

Further information on the movement of special or hazardous waste is available from the SEPA website:

http://www.sepa.org.uk/waste/waste_regulation/special_waste.aspx

Treatment of waste medical devices at the medical practice

Disinfection, decontamination or other treatment of infectious waste, to render it non-infectious, would normally require either a waste management licence (WML) granted in accordance with the Environmental Protection Act 1990 or a PPC Permit granted in accordance with the Pollution Prevention and Control Regulations 2012.

However, under the Waste Management Licensing (Scotland) Regulations 2011 an exemption from the requirement to hold a WML may be available if the waste medical devices are being sterilised (including those classified as special waste) in an autoclave at the medical practice where they were used ("the place of production"). There are specific conditions which must be satisfied in order for the exemption to apply e.g.

- only waste of the types listed in paragraph 28, Schedule 1 of 2011 Regulations may be treated,
- the capacity of the autoclaves must not exceed 3 cubic metres,
- the autoclaves must accredited by the Medicine and Healthcare Products Regulatory Agency ("the MHRA")

- no more than 100 tonnes of waste may be sterilised at any one place in any one calendar month, and
- where the waste is special waste, it is must be sterilised as part of, or as a preliminary to, a recovery operation.

Further information on the exemption and how to register is available from the SEPA website:

http://www.sepa.org.uk/waste/waste_regulation/application_forms/exempt_activities.aspx

Where the conditions of the exemption cannot be met the treatment of the waste by sterilisation would require a PPC permit or WML.

Any disinfection of infectious waste would need to demonstrate, as a minimum, the STAATT III standard for microbial inactivation.

Waste Exports for Recovery and Re-use

The export of waste from the United Kingdom for recovery is subject to both national and European Regulations on the transfrontier Shipment of Waste.

Special/Hazardous waste and waste destined for recovery in a developing country is generally subject to notification procedures which requires the prior written consent of all relevant authorities of dispatch, transit and destination.

Non-hazardous (Green list) waste can be shipped for recovery within OECD (Organisation for Economic Co-operation and Development) countries under a lower level of control and accompanied by certain information.

The shipment of non-hazardous waste to non-OECD countries (i.e. developing countries) depends on which classification of waste the importing country accepts and which procedures it wants to apply.

The UK Government has also issued statutory guidance on Shipments of Waste[1].

The European Regulation ("the EU Regulation") is the principal regulation governing shipment of waste into, out of and through the European Union[2]. It is supplemented by The Transfrontier Shipment of Waste Regulations 2007 ("the Transfrontier Shipment Regulations") which contain procedural requirements for waste being exported from the UK for recovery or re-use.

The rules to be followed when exporting waste for recovery or reuse depend on the nature of the waste i.e. (hazardous or non-hazardous) and whether the waste type can be identified in the list of wastes set out in the Annexes to the EU Regulation.

Not all wastes are listed in the Annex to the European Regulations, Cardiac catheters, for example, are not specifically identified and are classed as an 'unlisted waste'.

The export of non-listed waste for recovery or re-use is subject to the prior written notification consent procedure. This procedure requires consent from the national authorities in the country where the waste is produced (in Scotland this is SEPA), the country where it is destined for recovery or re-use and any country through which it is moved on it's way to it's final destination.

If the un-listed waste, for ex. catheter, is to be dispatched from the medical practice directly to a recovery facility overseas, a separate notification will be required for each medical practice of origin.

Further information and guidance on exporting notified wastes and the Transfrontier Shipment Regulations can be obtained from:

http://www.sepa.org.uk/waste/waste_regulation/transfrontier_shipment.aspx

MHRA guidance on reuse of single use devices

The MHRA has issued guidance on 'Single-use Medical Devices: Implications and Consequences of Reuse' which is available from:

[1] UK Plan for Shipment of Waste - http://www.doeni.gov.uk/niea/waste-shipments.pdf
[2] Regulation (EC) No 1013/2006 on of the European Parliament and the Council of 14 June 2006 on shipments of waste

http://www.mhra.gov.uk/home/groups/dts-iac/documents/publication/con2025021.pdf

SEPA Advice to medical practices

- You should ensure that any treatment, movement, disposal or export of waste medical devices is in accordance with environmental legislation.
- We recommend that medical practices view their procedures in relation to the management of waste medical instruments paying particular attention to non-listed wastes (for ex. catheters)
- If you have any concerns you should contact SEPA prior to treating, moving, disposing or exporting any waste of this type.

You should refer to the MHRA guidance for advice on reuse of single use devices.

Finally

This guidance applies only in Scotland and is based on current understanding. The terms of this guidance may be subject to periodical review and be changed or withdrawn in light of technological developments, regulatory or legislative changes, future government guidance or experience of its use.