

NHSScotland
Guide to the Carriage of Dangerous
Goods Regulations with respect to
Used Medical Devices

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1. Introduction

- 1.1 This guidance document has been produced by Health Facilities Scotland (HFS).

Who is this Guidance for?

- 1.2 This guidance has been produced to assist those involved with, or responsible for, the transportation of used medical devices to Central Decontamination Units (CDU), Endoscope Decontamination Units (EDU) and Local Decontamination Units (LDU).
- 1.3 It has been produced from the perspective of the 'consignor', that is the person who has the designated responsibility, for returning used medical devices to CDUs, EDUs or LDUs for decontamination.
- 1.4 This guidance should be used to inform decisions about the transport of used medical devices after domiciliary visits by clinicians.

Aim of the guidance

- 1.5 It aims to provide the reader with information regarding the key elements associated with the relevant Dangerous Goods Regulations by road, by air and sea applicable to used medical devices which are being returned to CDUs, EDUs or LDUs for decontamination. It also includes transport within NHSScotland premises and pavements.

2. Regulations and enforcement

- 2.1 With respect to transport by road; the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009) amended to implement the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).
- 2.2 The current version of ADR is ADR 2013.
- 2.3 The Department for Transport (DfT), Dangerous Goods Branch formulates CDG Regulation in the UK, with the Health and Safety Executive (HSE) as the enforcement agency. Police Scotland and the Vehicle Operators Services Agency are responsible for roadside enforcement.
- 2.4 With respect to transport by sea, the Merchant Shipping (Dangerous Goods and Maritime Pollutants) Regulations 1997 implement the International Maritime Dangerous Goods (IMDG) Code. The current version of IMDG is 2010.
- 2.5 The Merchant Shipping (Dangerous Goods and Maritime Pollutants) Regulations are enforced by the Maritime and Coastguard Agency (MCA).
- 2.6 Legal requirements for the carriage of dangerous goods by air are contained within the Air Navigation (Dangerous Goods) Regulations (AN(DG)Rs). The AN(DG)Rs place responsibility for the safe carriage of dangerous goods on all parties involved in the transportation. This is inclusive of passengers, shippers, freight forwarders, aircraft operators and couriers and they are required to meet the requirements as stipulated within the International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.
- 2.7 Transport via pavement and NHSScotland premises is covered by the general Health & Safety Regulations.

3. Roles

3.1 The Regulations apply to:

- consignors;
- loaders;
- packers;
- fillers;
- carriers and;
- drivers involved in the carriage of dangerous goods by road.

This includes NHS Boards, the contractors and the independent practitioners providing NHS healthcare services who are generally involved in some if not all of the above activities.

Dangerous goods security

3.2 All persons involved in the carriage of dangerous goods should consider the security requirements associated with the substances; consideration should be given to the appropriateness of:

- the carrier;
- any temporary storage sites, vehicles and depots;
- staff responsible for the carriage of such goods.

Consignor responsibilities

3.3 A consignor is defined as the person who has designated responsibility for returning used medical devices to the decontamination facility either on their own behalf or for a third party.

3.4 This means that all NHS bodies, independent contractors and third party providers that transport used medical devices, must comply with relevant parts of dangerous goods legislation. This responsibility does not transfer to a contracted carrier.

4. Classification of used medical devices

- 4.1 The classification of used medical devices is the same in road, air and sea regulation.
- 4.2 Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, Merchant Shipping (Dangerous Goods and Maritime Pollutants) Regulations and Air Navigation (Dangerous Goods) Regulations (AN(DG)Rs), reference nine different UN classes of dangerous goods, some of which are sub-divided into different divisions:
- Class 1 Explosives;
 - Class 2 Gases (Flammable gas, Toxic gas, Non Flammable Non Toxic Gas);
 - Class 3 Flammable Liquids;
 - Class 4.1 Flammable Solids;
 - Class 4.2 Spontaneously Combustible Materials;
 - Class 4.3 Dangerous when Wet;
 - Class 5.1 Oxidizing Substances;
 - Class 5.2 Organic Peroxides;
 - Class 6.1 Toxic Substances;
 - Class 6.2 Infectious Substances;
 - Class 7 Radioactive Materials;
 - Class 8 Corrosive Substances;
 - Class 9 Miscellaneous dangerous substances and articles.
- 4.3 Used medical devices are either known or presumed to pose a risk of infection and are therefore classified in Class 6.2: Infectious Substances.
- 4.4 Infectious substances are broadly divided into two groups, based on the level of infection posed, by reference to two hazard categories:
- Category A Highly infectious substance ([Appendix A](#));
 - Category B Infectious substance.

- 4.5 Used medical devices are Category B infectious substances and the following classification and descriptions should be used:

UN Class: 6.2

UN Number: UN 3291

Proper Shipping Name (PSN): Clinical Waste, Unspecified, (Used medical devices) NOS*

UN Packing Group (PG): II

For UN 3291 substances, an 'infectious substance' symbol, as [Figure 1](#), should be displayed on the container.



Figure 1

- 4.6 Contamination with infectious substances in Category A is very rare and contaminated items should not be routinely returned to CDU, EDU or LDU, due to their highly infectious nature. [Appendix A](#) contains a list of Category A pathogens and further guidance.
- 4.7 This guide is applicable for used medical devices classed as Category B Infectious Substances.
- 4.8 In addition to used medical devices, CDUs, EDUs and LDUs may be responsible for the transportation of other dangerous goods, such as disinfectant and cleaning agents. The regulatory requirements applicable to these substances are not included within this guide. This guide reviews the requirements with respect to used medical devices only. Advice should be sought from the manufacturers and/or suppliers of dangerous goods in the first instance with additional advice being provided by a Dangerous Goods Safety Advisor (DGSA).
- 4.9 A qualified DGSA can help in the identification and classification of dangerous goods. NHS Boards should have a DGSA appointed to conduct statutory requirements and provide an annual report and access to DGSA advice on an ongoing basis.

5. Transport of used medical devices by road

- 5.1 ADR 2013 states that medical devices or equipment potentially contaminated with or containing infectious substances (other than those classified in Category A) carried for the purpose of cleaning, disinfection, sterilization, repair or equipment evaluation do not need to be classified as infectious waste and are not subject to the full requirements of ADR provided that:
- they are packaged in such a way that under normal conditions of carriage they cannot break, be punctured or leak. The packages are designed to meet the construction requirements listed in ADR sections 6.1.4 or 6.6.4;
 - the packaging meets the general packaging requirements of ADR sections 4.1.1.1. and 4.1.1.2 and be capable of meeting the drop test requirements of 1.2m;
 - and the packaging shall be marked 'USED MEDICAL DEVICE' or 'USED MEDICAL EQUIPMENT.'
- 5.2 In summary, as long as the packaging and labeling requirements of ADR 2013 are met, the carriage of used medical devices by road is not subject to any other requirements of ADR or the CDG Regulations. This means that the CDG requirements with respect to documentation, vehicle equipment and weight markings, and driver training do not apply.

Approved packaging and labeling for road transport

- 5.3 Whilst ADR 2013 does not specifically require that the packaging must be marked as UN tested and approved; it provides a practical way of demonstrating that the packaging meet the ADR requirements.
- 5.4 Packing Instruction P621 (individual packages) requires that:
- packages should be rigid and should contain sufficient absorbent material or be leak proof to prevent the entire amount of free liquid escaping;
 - packaging intended to contain sharp objects such as broken glass and needles shall be resistant to puncture and retain liquids under the performance test conditions.
- 5.5 When a package has successfully undergone testing and is classified as 'UN Approved' it is allocated a code, the most important part of which is the symbol noted in [Figure 2](#) which is given at the start of the code:



Figure 2:UN Type Approval Mark

- 5.6 UN approved packaging should bear the symbol in [Figure 2, section 5.5](#), either in the form of a label attached to the packaging (e.g. a sticker) or the symbol may be embossed into the packaging itself.
- 5.7 UN approvals are type-specific e.g. packaging is given type approval for specific classification(s) of dangerous goods. Medical devices or equipment potentially contaminated with or containing infectious substances (other than those classified as Category A), should be packaged in packaging approved for infectious substances; packing instructions P621 (individual packages) as shown in [Figure 3](#) and LP621 (wheeled bins and trolleys) as shown in [Figure 4](#).



Figure 3: Examples of P621 individual packaging showing location of UN approved marking.

- 5.8 Packing instruction LP621 (wheeled bins and trolleys) requires that: For packages containing large quantities of liquids, rigid packages conforming to test requirements for liquids shall be used.
- 5.9 Where UN approved trolleys (LP621) are used, the internal storage containers (if used) within the trolleys need not be UN approved.



Figure 4: example of LP621 Transportation Cart.

- 5.10 Care should be taken when procuring containers for used medical devices. Not all trolleys are UN approved and therefore have not been tested to ensure

compliance with LP621. Whilst it is acknowledged that many of these trolleys are 'fit for purpose' (designed for their purpose), procurement policy should be such that only 'UN approved' containers are purchased.

Best practice for road transport

- 5.11 Clear segregation is required for packaging (boxes) used for 'clean-ready to use' and 'dirty' instruments. Containers should be subjected to cleaning and/or disinfection process between uses.
- 5.12 Packaging should be clearly labeled with identification of recipient as shown in [Figure 5](#).



Figure 5:Packaging showing clear label

- 5.13 ADR 2013 also removes the requirement for the vehicle to show the appropriate plates notifying road users that they are carrying dangerous goods

Although drivers of vehicles carrying dangerous goods under 333kg do not need to hold an ADR Vocational Training Certificate (VTC). HFS recommends that where possible drivers with a VTC qualification are assisted to retain this and new drivers are encouraged to gain their VTC. However, it is acknowledged that obtaining a VTC requires significant financial and time investment and where drivers are not solely employed to transport used medical devices this may not be practical.

6. Transport of used medical devices by sea

- 6.1 Transporting used medical devices by sea (including inter-island ferry services) must comply with the full requirements of IMDG and no relaxation is given.

Approved packaging for sea transport

- 6.2 The packaging requirements for sea transport are identical to the packaging requirements for road transport, refer to sections 5.3-5.12.

Marking and labeling of container

- 6.3 Each container bearing dangerous goods should have a label identifying the type of goods contained by reference to the appropriate UN number (UN 3291) and should show the appropriate label (hazard warning symbol, [Figure 1](#)).
- 6.4 Labels must have minimum dimensions of 100mm x 100mm or where a package is of such an irregular shape or small size where a label cannot be affixed, the label may be attached by a securely affixed tag or by other suitable means.
- 6.5 The labels (hazard warning symbol) are usually shown on a white background. However, the label may be embossed on a package without the background colour being white in line with the Department of Transport Authorisation Letter No 53.
- 6.6 Dangerous goods labels must only be used on contaminated goods and therefore labels should be removed from packages when the package contains clean items only.
- 6.7 Packaging should be clearly labelled with identification of recipient (refer to [section 5.12](#)).

Transport document

- 6.8 A transport document is not required for the road portion of the transport if the used medical devices are carried in accordance with ADR 2013 (see section 3.9 in the ADR). However, a transport note is required for carriage by sea. Blank notes can be downloaded from the Maritime and Coastguard Agency (MCA) web site: http://www.dft.gov.uk/mca/blank_dgn-2.pdf

Driver Training

- 6.9 Drivers of vehicles carrying dangerous goods weighing 333kg or more (regardless of the weight of the vehicle) must hold an ADR (VTC) issued by the DfT / DVLA stating that they have attended and passed an examination(s).

Vehicle markings

- 6.10 Vehicles carrying loads less than 333kg (excluding the weight of the trolley) are not required to show specific dangerous goods marking. However, all packages on the vehicle must be appropriately labelled. See section 6.3
- 6.11 Plain orange plates are required to be displayed on the front and rear of the vehicles carrying in excess of 333kg of used medical devices (excluding the weight of the trolley). These must be rectangular reflective orange plates (400 mm x 300mm with a black border of 15mm) and clearly visible. See Figure 6.

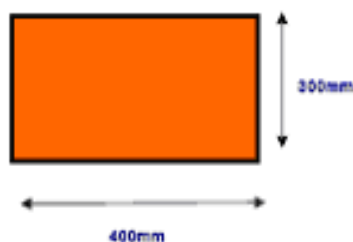


Figure 6: Reflective orange plate

- 6.12 If the size and construction of the vehicle are such that the available surface area is insufficient to affix these plates then the dimensions can be reduced to 300mm for the base, 120mm for the height and 10mm for the black border.
- 6.13 The orange plates should be removed or 'folded away' when the vehicle is not carrying dangerous goods.

Vehicle equipment

- 6.14 Vehicles carrying used medical devices must carry at least one portable fire extinguisher with a minimum capacity of 2kg dry powder suitable for fighting a fire in the engine or cab of the vehicle.
- 6.15 Each vehicle (carrying in excess of 333kg) must have:
- at least one wheel chock or scotch of a size suitable for the weight of the vehicle;
 - two self standing warning signs (e.g. reflective cones, triangles or flashing);
 - amber lights, which are independent from the vehicle's electrical equipment);
 - suitable warning vest or warning clothing for each member of the vehicle crew;
 - a pocket lamp for each member of the vehicle crew;
 - the personal protection equipment necessary to take the additional or special actions referred to in the instructions in writing;
 - no passengers other than members of the vehicle crew may be carried;

- the crew of the vehicle must know how to operate the fire fighting equipment;
- a driver or driver's assistant must not open a package containing dangerous goods;
- the parking brake must be applied to the vehicle when parked;
- if any substances have leaked and been spilled in a vehicle or container, it may not be re-used until after it has been thoroughly decontaminated.

Additional requirements and best practices

- 6.16 For domestic voyages of Class 6.2 substances, including used medical devices instruments, carried as UN 3291: Clinical waste, where no other service exists other than on board passenger ferries, stowage category E is approved, away from living quarters and preferably under deck. All other conditions of the IMDG Code must apply to such goods, including the correct labeling of the goods and placarding of cargo transport units.
- 6.17 When transporting used medical devices, carried as UN 3291, the vehicle is to be accompanied by the driver of the vehicle unless the Competent Authority have given approval to allow unaccompanied vehicles.
- 6.18 Clear segregation is required for packaging (boxes) used for 'clean' and 'dirty' instruments. Containers should be subjected to cleaning and/or disinfection process between uses.

7. Transport of used medical devices by air

- 7.1 Given the remote nature of many of Scotland's health facilities, the transportation of used medical devices by air may be a viable option.

Approved packaging for air transport

- 7.2 The UK legal requirements for the carriage of dangerous goods by air are contained within the Air Navigation (Dangerous Goods) Regulations (AN(DG)Rs) 2012. Shippers of dangerous goods are ultimately responsible for ensuring that any dangerous goods they intend to transport by air are: not prohibited, are correctly classified, packed, marked, labelled and declared as required by the ICAO technical Instructions.

If the used medical device is being transported for the purposes of decontamination then they are not subject to section 6.3 of the ICAO Technical Instructions i.e.

“Packed in packaging designed and constructed in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents”.

Packaging must be designed to meet the construction requirements listed in the ICAO Technical instructions section 6.3.2.3.7.1 and 4.1 (with the exception of section 4.1.1.4.1) i.e.

“If the outer packaging is not liquid tight and the medical devices or equipment are contaminated with or contain liquid infectious substances, a means of containing the liquid in the event of leakage must be provided in the form of a leak proof liner, plastic bag or other equally effective means of containment. These packaging must be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m.”

- 7.3 Packages must be marked “Used medical device”. When an over-pack is used, it must also be marked with the words “Used medical device” unless the inner markings are visible.

Note: Individual airlines may apply their own policies which may be more stringent than applicable international transport regulations.

Training

- 7.4 Training is required for shipping Category B substances. Shippers and packers are required to undergo dangerous goods by air training commensurate with their responsibilities. Further advice is available from the ICAO website.

8. Pedestrian Transport and Transport within Internal NHSScotland Premises

- 8.1 While specific legislation and guidance covering internal and pedestrian transport is not available, it is important to remember that legislations such as Health and Safety at Work (1974), Personal Protective Equipment at Work (1992) and Management of Health and Safety at Work (1999) obligate employers and employees to consider the risks associated with transport of used medical devices. It is therefore recommended internal and pedestrian transport of used medical devices practice would reflect the principles outlined in ADR 2013 and in [section 5](#) of this guidance.

Abbreviation and Glossary

ADR	l'Accord européen relatif au transport international des marchandises Dangereuses par Route. The European agreement concerning the carriage of dangerous goods by road.
CDU	Central Decontamination Unit.
CHIP	Chemicals (Hazard Information and Packaging) Regulations 1994.
Clinical waste	Any waste which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, pharmaceuticals, dressings, sharps etc.
Consignee	The receiver of the dangerous goods.
Consignment Note	The Transport document used for the carriage of Hazardous Wastes in the UK.
Consignor	The sender of the dangerous goods.
COSHH	Control of Substances Hazardous to Health.
COTC	Certificate of Technical Competence.
DfT	Department for Transport.
DGN	Dangerous Goods Note.
DGSA	Dangerous Goods Safety Adviser.
Hazard class	Nine divisions of dangerous goods determined by their primary risk.
HSE	Health and Safety Executive.
IATA	International Air Transport Association.

IBC	Intermediate Bulk Container.
IMDG	International Maritime Dangerous Goods.
Infectious substance	Substances which are known or are reasonably expected to contain pathogens.
Label	A diamond shape indicating a UN hazard class.
LDU	Local Decontamination Unit.
Limited Quantities	A method of carrying dangerous goods that are exempted from most legislation by virtue of the small volumes in each package.
MCA	Maritime and Coastguard Agency.
NOS	Not Otherwise Specified.
Packing Group	A method of indicating varying risks posed by different substances within a single UN class. PGI- most dangerous, PGII – medium danger, PGIII – Least danger.
Placard	Essentially a large chemical hazard diamond attached to a vehicle or tank.
PSN	Proper Shipping Name.
Risk Group	A method of subdividing Infectious substances in accordance with their risk.
Transport Category	Materials are assigned to a category of 0-4 in order to determine the Load Limits at which regulation is applied.
UN Class	Allocation of substances according to the main hazard danger.
UN Number	An internationally recognised four-digit identification number for an item of dangerous goods.
VTC	Vocational Training Certificate.

Appendix A: Category A Infectious Substances

It is highly unlikely that Decontamination Units will encounter highly infectious materials classified as Category A in Carriage Regulations. Such materials should not be accepted without necessary precautions being taken to protect staff and the public. Specific advice should be sought on a case-by case basis from suitably qualified infection control teams and the HSE. If such material is transported to Central Decontamination Units a police escort may be necessary.

The table, shown below, shows the indicative pathogen/disease list for Category A substance affecting humans (classified as UN 2814) and animals (classified as UN 2900).

INDICATIVE EXAMPLES OF INFECTIOUS SUBSTANCES INCLUDED IN CATEGORY A IN ANY FORM UNLESS OTHERWISE INDICATED
UN Number and name Micro-organism

UN 2814

Bacillus anthracis (cultures only)
 Infectious substances Brucella abortus (cultures only)
 affecting humans Brucella melitensis (cultures only)
 Brucella suis (cultures only)
 Burkholderia mallei - Pseudomonas mallei – Glanders (cultures only)
 Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)
 Chlamydia psittaci - avian strains (cultures only)
 Clostridium botulinum (cultures only)
 Coccidioides immitis (cultures only)
 Coxiella burnetii (cultures only)
 Crimean-Congo haemorrhagic fever virus
 Dengue virus (cultures only)
 Eastern equine encephalitis virus (cultures only)
 Escherichia coli, verotoxigenic (cultures only)
 Ebola virus
 Flexal virus
 Francisella tularensis (cultures only)
 Guanarito virus
 Hantaan virus
 Hantaviruses causing haemorrhagic fever with renal syndrome
 Hendra virus
 Hepatitis B virus (cultures only)
 Herpes B virus (cultures only)
 Human immunodeficiency virus (cultures only)

UN Number and name Micro-organism**UN 2814 (continued)**

Highly pathogenic avian influenza virus (cultures only)

Japanese Encephalitis virus (cultures only)

Junin virus

Kyasanur Forest disease virus

Lassa virus

Machupo virus

Marburg virus

Monkeypox virus

Mycobacterium tuberculosis (cultures only)

Nipah virus

Omsk hemorrhagic fever virus

Poliovirus (cultures only)

Rabies virus (cultures only)

Rickettsia prowazekii (cultures only)

Rickettsia rickettsii (cultures only)

Rift Valley fever virus (cultures only)

Russian spring-summer encephalitis virus (cultures only)

Sabia virus

Shigella dysenteriae type 1 (cultures only)

Tick-borne encephalitis virus (cultures only)

Variola virus

Venezuelan equine encephalitis virus (cultures only)

West Nile virus (cultures only)

Yellow fever virus (cultures only)

Yersinia pestis (cultures only)

UN No. 2900

Infectious African swine fever virus

substances African swine fever virus

affecting animals Avian paramyxovirus Type 1 – Velogenic only

Newcastle disease virus

Bluetongue virus

Classical swine fever virus

Foot and mouth disease virus

Lumpy skin disease virus

Mycoplasma mycoides - Contagious bovine pleuropneumonia

Peste des petits ruminants virus

Rinderpest virus

Sheep-pox virus

Goatpox virus

Swine vesicular disease virus

Vesicular stomatitis virus

References

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<http://www.caa.co.uk/default.aspx?catid=1219&pageid=9600>