NHS National Services Scotland

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

Scottish Health Technical Memorandum 01-03

SHTM 01-03

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NHSScotland Assure
Quality in the healthcare environment

Contents

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Executive summary

In 2013 Health Facilities Scotland (HFS) now part of NHSScotland Assure, published Version 1 of GUID 5006 - Guide to the Carriage of Dangerous Goods Regulations with respect to Used Reusable Medical Devices (RMDs). The revision of GUID 5006 version 1.0 is required due to changes in the regulations applicable to GB, that is England, Scotland and Wales, as a result of the United Kingdom's exit from the European Union as outlined in the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (CDGUTPE) (Amendment) (EU Exit) Regulations 2020 (see ref 1). In addition, the title of this document has been changed to Scottish Health Technical Memorandum (SHTM) 01-03 to better align this reusable medical device decontamination guidance with other parts of the SHTM 01 series.

This guidance aims to provide the reader with information on the key elements associated with the relevant Dangerous Goods Regulations as applicable to RMDs being returned to Central Decontamination Units (CDUs), Endoscope Decontamination Units (EDUs) and Local Decontamination Units (LDUs) for decontamination. This guidance should also be used to inform decisions about the transport of used medical devices after domiciliary visits by clinicians.

This guidance has been produced to assist those involved with, or responsible for, the transportation of used medical devices within NHSScotland health boards, including contractors and independent practitioners providing NHS healthcare services.

Carriage of dangerous goods by road or rail is regulated internationally by the 'United Nations Economic Commission for Europe, (UNECE) European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2023' (see ref 2). The regulations are regularly updated by the membership of the Economic Commission for Europe Inland Transport Committee to take account of technological advances.

SHTM 01-03 also provides information on transportation packaging requirements and how to ensure safe transportation of used RMDs both within NHS health boards premises and more widely when transported via public roads, railways, ferry services or internal flights.

1. Introduction

Background

1.1. In 2013 Health Facilities Scotland (HFS) now part of NHSScotland Assure, published Version 1 of GUID 5006 - Guide to the Carriage of Dangerous Goods Regulations with respect to Used Reusable Medical Devices (RMDs). The revision of GUID 5006 version 1.0 is required due to changes in the regulations applicable to GB, that is England, Scotland and Wales, as a result of the United Kingdom's exit from the European Union as outlined in the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (CDGUTPE) (Amendment) (EU Exit) Regulations 2020 (see ref 1).

1.2. In addition, the title of this document has been changed to Scottish Health Technical Memorandum (SHTM) 01-03 to better align this reusable medical device decontamination guidance with other parts of the SHTM 01 series.

Who is this Guidance for?

1.3. 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) including:

- consignors
- loader
- packers
- fillers
- carriers and
- drivers involved in the CDGs by road

1.4. 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.

1.5. This guidance should be used to inform decisions about the transport of used medical devices after domiciliary visits by clinicians.

Aim of the guidance

1.6. This guidance aims to provide the reader with information on the key elements associated with the relevant Dangerous Goods Regulations as applicable to RMDs being returned to CDUs, EDUs and LDUs for decontamination. SHTM 01-03 also provides information on

transportation packaging requirements and how to ensure safe transportation of used RMDs both within NHS health boards premises and more widely when transported via public roads, railways, ferry services or internal flights.

2. Regulations and enforcement

2.1. Carriage of dangerous goods by road or rail is regulated internationally by the 'United Nations Economic Commission for Europe, (UNECE) European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2023' (see ref 2). The regulations are regularly updated by the membership of the Economic Commission for Europe Inland Transport Committee to take account of technological advances.

2.2. The most recent revision of the Agreement includes amendment to Annexes A and B and has been published as document ECE/TRANS/326, Vol. I and II (ADR 2023) (see ref 2).

2.3. Article 2 of the ADR 2023 (see ref 2) states that: "*apart from certain classes of 'excessively' dangerous goods, other dangerous goods may be carried internationally in road vehicles subject to*

- the conditions laid down in Annex A for the goods in question, in particular as regards their packaging and labelling; and

- the conditions laid down in Annex B, in particular as regards the construction, equipment and operation of the vehicle carrying the goods in question"

2.4. New safety requirements are implemented by member states via domestic regulations. Therefore, the security provisions when traveling within the UK are regulated through regulation five of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (CDGUTPE) Regulations 2009 (see ref 1) which incorporates the:

- European Agreement concerning the ADR (2009) ass amended (see ref 3):
    - the Annex to the Regulation concerning the International Carriage of Dangerous Good by Rail (RID) which forms Appendix C to the Convention concerning International Carriage by Rail ("COTIF") (Current Edition: 2009) (see ref 3)
    - the Regulations annexed to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway ("ADN") (Current edition: 2009) (see ref 4)
    - International Management of Dangerous Goods (IMDG) (see ref 5) as defined by the Territorial Sea Act 1987 (see ref 6)
    - carriage of dangerous goods by air are contained within the Air Navigation (Dangerous Goods) (Amendment) Regulations (AN(DG)Rs) 2021 which came into force on the 29 June 2021 (see ref 7)

2.5. As of the 1st of January 2021, these regulations were amended by The Carriage of 'Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) (EU Exit) Regulations 2020' regulations seven and eight (see ref 1) which contain additional security provisions that apply in GB.

2.6. A range of agencies have responsibility for enforcement of the regulations within GB including:

- the Department for Transport (DfT) - responsible for the enforcement of the secure CDGs requirements (excluding class 7 radioactive materials) by road rail or inland waterways (see ref 8)
- the Vehicle Certification Agency (VCA) Dangerous Goods Office - responsible for the certification of dangerous goods packaging within the UK (see ref 9)
- UK Civil Aviation Authority - responsible for transportation of dangerous goods by Air (see ref 7)
- Maritime and Coastguard Agency (MCA) - Executive Agency of the DfT, and responsible throughout the UK for implementing the government's maritime safety policy for internal waterways and at sea (see ref 1)

3. Scope

3.1. This guide reviews the requirements applicable to used Reusable Medical Devices (RMDs) being returned to Central Decontamination Units (CDUs), Endoscope Decontamination Units (EDUs) and Local Decontamination Units (LDUs) for decontamination including:

- relevant transportation of dangerous goods regulations by road, rail, by air and sea
- approved transportation packaging
- transport within NHSScotland premises and pavements

3.2. As applicable to:

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

3.3. 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.

Out of scope

3.4. Guidance for disposal of used single use or reusable devices being sent for disposal as clinical waste. Additional guidance on waste management can be found in Scottish Health Technical Note (SHTN) 03 series - NHSScotland Waste Management Guidance SHTN 03-01 Version 7.0 2023 (see ref 10).

3.5. Used medical devices considered as Category A: infectious substance under UN regulations (see ref 11) can include:

“carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease in otherwise healthy humans or animals.”

3.6. Samples of materials such as blood, tissue, excreta, secreta, collected from humans or animals considered as, category B infectious substances (see ref 11).

3.7. The regulatory requirements applicable to transportation of other dangerous goods, such as disinfectant and cleaning agents, are not included within this guide. 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. Role and responsibilities

Dangerous goods security

4.1. All persons involved in the carriage of used Reusable Medical Devices (RMDs) should consider the security requirements associated with the items during transportation. 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

4.2. 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.

4.3. 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.

5. Staff and patient safety

5.1. When transporting used Reusable Medical Devices (RMDs) it is vital that there is clear segregation of packaging (boxes) used for 'clean' and 'dirty' instruments. Containers should be subjected to cleaning and/ or disinfection process between uses (see ref 12). Used devices are also required to be:

- held in secure transportation trollies or other approved containers
- kept separate from other goods being transported in the same vehicle

5.2. When handling sharp or contaminated medical devices It is essential that the correct personal protective equipment is provided and worn. This will minimise any potential risk of infection or sharps injuries to individuals who must handle them, or the public and minimise damage to unsecured devices.

5.3. The control of occupational exposure to biological agents in the healthcare setting is covered by the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (see ref 13) which should be followed.

5.4. Most used RMDs being sent for decontamination are considered a low infection risk under the UN infectious substances regulations and are assigned to category UN 3373 or UN3291 clinical waste (see ref 11 and14) except for medical devices and specimens known to be contaminated with Category A infectious organisms (see ref 11). The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (2009) as amended in 2023 (see ref 2) states:

"where 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."

5.5. Therefore, as long as the packaging and labelling requirements of ADR 2023 (see ref 2) and any additional requirements of the Department for Transport (DfT) GB approval mark (see ref15) are met, the carriage of used medical devices by road is not subject to any other requirements of the ADR (see ref 2) or CDG Regulations (see ref 1 and 2) with respect to:

- documentation

- vehicle equipment
- weight markings
- driver training

5.6. The DfT has published detailed guidance on the requirements for the carriage of goods by road and rail on their website (see ref 14 and 15).

5.7. When contaminated medical devices need to be transported by sea (including inter-island ferry services) for decontamination the packaging and transportation containers must comply with the full requirements of International Management of Dangerous Goods (IMDG) (see ref 5) and no relaxation is given.

5.8. The UK legal requirements for the CDGs by air are contained within the Air Navigation (Dangerous Goods) (Amendment) Regulations (AN(DG)Rs) 2021 which came into force on the 29 June 2021(see ref 7).

6. Approved packaging and labelling

6.1. In the UK the Vehicle Certification Agency (VCA) is responsible for issuing Performance Certificates to packaging and Intermediate Bulk Containers (IBCs). These have been successfully tested by an accredited test body (see ref 15 and 16) in accordance with the UN Model Regulations on the transportation of dangerous goods Model Regulations Volume 1 2019 (see ref 17).

6.2. Although it is acknowledged that many trolleys on the GB market are 'fit for purpose' (designed for their purpose), care should be taken when procuring containers for used Reusable Medical Devices (RMDs) as not all trolleys on the market are UN and/ or GB approved. That is, have been tested by one of fifteen authorised test stations (see ref 15) and awarded a UN performance certificate and official GB mark.

6.3. While International Carriage of Dangerous Goods by Road (ADR) 2023 (see ref 2) does not specifically require that the packaging must be marked as UN approved, it provides a practical way of demonstrating that packaging will meet the ADR requirements including packing Instruction P650 for individual packages (see ref 15) which 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

6.4. In the UK the VCA is responsible for issuing Performance Certificates to packaging and IBCs. These have been successfully tested by an accredited test body (see ref 15 and 16) in accordance with the UN Model Regulations on the transportation of dangerous goods Model Regulations Volume 1 2019 (see ref 17). The VCA also:

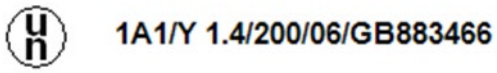
- allocate unique GB and UN approval marks, which are recognised multi-modally throughout the world
- maintain records of all UN packaging approvals issued by the UK
- operate a quality assurance program involving the periodic inspection of production examples of UN approved packaging
- publish operational instructions for United Kingdom Accreditation Service (UKAS) accredited 'Test Stations', detailing the methods and procedures which must be followed when testing dangerous goods packaging and IBCs
- advise on the use of dangerous goods packaging

6.5. Therefore, any local procurement policy should be such that only 'UN and/ or GB marked approved' containers are purchased.

6.6. After a specific design of package has successfully undergone testing and is classified as 'UN Approved' it is given a symbol and code which can be applied either in the form of a

label attached to the packaging or the symbol may be embossed into the packaging itself. An example of the approved symbols can be seen in Figure 6.1.

Figure 6.1 - UN approval mark



6.7. UN packaging approvals are ‘type-specific’ that is packaging is given ‘type approval’ for specific classification(s) of dangerous goods. For example, medical devices or equipment potentially contaminated with, or containing infectious substances (other than those classified as Category A (see ref 11, 14 and appendix A)), should be packaged as required by packing instructions P650 (see ref 17). Examples of an individual package approved for infectious substances is shown in Figure 6.2.

Figure 6.2 - An example of a small container suitable for containment of used RMDs during transport

For packages containing large quantities of liquids, rigid packages conforming to test requirements for liquids should be used. Where UN approved trolleys (LP621) (see ref 17) are used, any internal storage containers within the trolleys need not be UN approved. Examples of UN approved LP621 trolleys are shown in Figure 6.3.

Figure 6.3 - An example of a large metal transport trolley for transportation of multiple RMDs

6.8. All transport containers and packages on the vehicle must be clearly labelled with the identity of the intended recipient and where required have clear segregation of ‘clean-ready to use’ and ‘dirty’ used instruments.

6.9. Within GB the certification of each UN approved packaging type must be revalidated at least once every 5 years (see ref 1 and 8). The new GB certificate number which is allocated to an approved package design type will remain with it for life (such as from one revalidation to the next) providing the package specification does not alter.

6.10. The certificate holder must ensure the correct code for the year of manufacture is shown in the mark applied to the packaging. Therefore, consigners and end-users should ensure that the packaging they are using is still valid for transportation and the approval certificate is up to date via the VCA database.

7. Transporting used medical devices by road

Vehicle markings

7.1. European Agreement concerning the International Carriage of Dangerous Goods by Road (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:

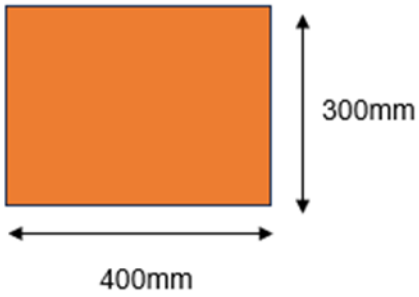
- they are packaged in such a way that under normal conditions of carriage they cannot break, be punctured or leak. The packages are designed to meet the construction requirements listed in ADR sections 6.1.4 or 6.6.4
- the packaging meets the general packaging requirements of ADR sections 4.1.1.1. and 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.'

7.2. Therefore, the ADR 2023 (see ref 2) removed the requirement for vehicles carrying loads less than 333kg (excluding the weight of the trolley) to display placarding and markings there will be differences in the way the regulations are applied depending on the substances being transported and the package size.

7.3. All packages on the vehicle must be appropriately labelled (see refs 12, 14 and 17) and where mixed loads are being transported the aggregation rules in ADR 2023 (see ref 2) to show specific dangerous goods marking apply. Plain orange plates must also be displayed on the front and rear of the vehicles.

7.4. Where vehicles carry in excess of 333kg (excluding the weight of the trolley) plain orange plates (see Figure 7.1) are required to be displayed on the front and rear of the vehicles. These must be rectangular reflective orange plates (400 mm x 300mm with a black border of 15mm) and clearly visible.

Figure 7.1 - example of reflective orange plate



7.5. 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. The orange plates should be removed or 'folded away' when the vehicle is not carrying dangerous goods.

Vehicle equipment

7.6. All vehicles carrying used medical devices classified as dangerous goods 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 (see ref 17 and 18). The requirement for at least one wheel chock or scotch of a size suitable for the weight of the vehicle has been removed from the requirements of the CDGs and Pressure Systems regulations: 2023 (see ref 1) as applicable in GB.

7.7. Each vehicle (carrying in excess of 333kg) must also have:

- two self-standing warning signs for example 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

The crew of the vehicle must know how to operate the firefighting equipment and 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. The driver or driver's assistant must not open a package containing dangerous goods.

The parking brake must be applied to the vehicle when parked.

No passengers other than members of the vehicle crew may be carried.

Driver Training

7.8. Drivers of vehicles carrying dangerous goods weighing 333kg or more (regardless of the weight of the vehicle) must hold an ADR (Vocational Training Certificate (VTC)) issued by the Department for Transport (DfT)/ Driver and Vehicle Licensing Agency (DVLA) stating that they have attended and passed - Dangerous Goods Security Training examination(s) (see ref 18).

7.9. Although drivers of vehicles carrying dangerous goods under 333kg do not need to hold an ADR VTC. NHSScotland Assure recommends that 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. Transportation by rail and inland waterways within GB should comply with the requirements of the ADR: 2023 (see ref 2).

8. Transporting used medical devices by sea

8.1. When Used Reusable Medical Devices (RMDs) need to be transported by sea (including inter-island ferry services) for decontamination, the packaging and transportation containers must comply with the full requirements of the International Maritime Dangerous Goods (IMDG) Code (see ref 5).

8.2. All packages on the vehicle must be appropriately labelled and must comply fully with the international arrangements for packaging for sea transport (see refs 12, 14 and 17), and no relaxation is given (See ref 5).

Approved packaging for sea transport

8.3. As used RMDs are presumed to pose a hazard from infection they are classed under 'Medical or clinical waste containing infectious substances, Class 6.2 which is further subdivided depending on the level of risk posed into:

- category A (UN No 2814 or, UN No 2900)
- category B (UN No 3291, 3373 or 3549)

additional information can be found in Appendix A.

Note 8.1: The United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals provides a list of organisms that are internationally recognised to posse a high risk of transmission and to be considered as Category A organism See ref 11).

8.4. Most Used medical devices are considered to be a low infection risk when packaged and transported correctly and are classified as Category B infectious substances for the purpose of packaging and labelling for transportation by sea. This means that they should be contained in a UN approved container type UN 3291 or 3373 (see ref 11 and 14) 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) (not otherwise specified (NOS))
- UN Packing Group (PG): II

8.5. For UN 3291 substances, an 'infectious substance' symbol, as Figure 8.1, should be displayed on the container.

Figure 8.1 - An example of a hazard warning symbol

8.6. Labels must have minimum dimensions of 100mm x 100mm or where a package is an irregular shape or small size and a label cannot be affixed, the label may be attached by a securely affixed tag, or other suitable means.

8.7. The labels for category B infectious substances (hazard warning symbol) are usually shown on a white background (Figure 8.1). However, the label may be embossed on a package without the background colour being white. The lower half of the label may bear the inscriptions: “INFECTIOUS SUBSTANCE” and “In case of damage or leakage immediately notify Public Health Authority”;

8.8. Dangerous goods labels must only be used on contaminated goods and therefore labels should be removed from packages when the package will be used to contain clean items.

8.9. Packaging should be clearly labelled with identification of the recipient (refer to section 6.8). All requirements of the IMDG for Vehicle equipment, vehicle markings and driver training must also be observed.

Note 8.2: Medical or clinical wastes assigned to number:

18 01 04 (Wastes from human or animal health care and/ or related research, that is wastes from neonatal care, diagnosis, treatment or prevention of disease in humans - wastes whose collection and disposal is not subject to special requirements in order to prevent infection) according to the list of wastes annexed to the Commission Decision 2000/532/EC5 as amended, are not subject to the provisions of International Carriage of Dangerous Goods by Road (ADR).

Transport documents

8.10. Where the used medical devices weigh under 333Kg a transport document is not required for the road portion of a journey within GB if carried in accordance with ADR 2023 (see ref 2). A transport note is required for any part of the journey via carriage by sea for example ferry crossings to the Western Isles. Further information can be found at the Maritime and Coastguard Agency (MCA) website.

Additional requirements and best practice

8.11. For domestic voyages of used RMDs, (see ref 1), including carried as UN 3291 Infectious waste Class 6.2 category B and where no other service exists other than on board passenger ferries, the vehicle should be:

- accompanied by the driver of the vehicle unless the Competent Authority have given approval to allow unaccompanied vehicles
- stowage away from living quarters and preferably under deck (category E) is approved

All other conditions of the IMDG Code, including the correct labelling of the goods and placarding of cargo transport units apply.

Driver training

8.12. Drivers of vehicles carrying dangerous goods weighing 333kg or more (regardless of the weight of the vehicle) must hold an ADR (Vocational Training Certificate (VTC)) issued by the Department for Transport (DfT)/ Driver and Vehicle Licensing Agency (DVLA) stating that they have attended and passed an examination(s).

Vehicle markings

8.13. 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 7.1).

8.14. 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.

8.15. The orange plates should be removed or ‘folded away’ when the vehicle is not carrying dangerous goods.

Vehicle equipment

8.16. 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.

8.17. 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 (such as 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

8.18. 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.

8.19. 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.

9. Transport of used medical devices by air

9.1. The UK legal requirements for the carriage of dangerous goods by air are contained within the Air Navigation (Dangerous Goods) (Amendment) Regulations (AN(DG)Rs) 2021 which came into force on the 29 June 2021 (see ref 7) and states:

"An impact Assessment has not been produced for this instrument as there is no material effect on business, charities or the voluntary sector."

9.2. Therefore, 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 International Civil Aviation Organisation (ICAO) technical Instructions (see ref 19).

9.3. If used medical devices are being transported for the purposes of decontamination, then they are not subject to section 6.3 of the ICAO Technical Instructions (see ref 19) when *"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".*

9.4. 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) which states

"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."

9.5. 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 (see ref 19).

Note 9.1: Individual airlines may apply their own policies which may be more stringent than applicable international transport regulations.

Training

9.6. 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.

10. Pedestrian transport and transport within internal NHSScotland premises

10.1. While specific legislation covering internal and pedestrian transport is not available, Guidance Scottish Health Planning Note (SHPN) 13 Part 1 Decontamination Facilities: Central Decontamination Unit: 2011 (see ref 20) includes operational policies on internal transportation and off-site transportation.

10.2. It is also important to ensure legislations such as Health and Safety at Work Act (1974), (see ref 21), Personal Protective Equipment at Work (1992) (see ref 22) and Management of Health and Safety at Work (1999) (see ref 23) are followed and that employers and employees obligations to consider the risks associated with transport of used medical devices is implemented. It is therefore recommended internal and pedestrian transport of used medical devices practice would reflect the principles outlined in International Carriage of Dangerous Goods by Road (ADR) 2023 (see ref 2) and section 5 of this guidance.

10.3. Where transport of hazardous or infectious waste arises from care activities, health care workers do not need to comply with the ADR clause 8.1.4.1 (see ref 2) requirement to carry a 2 kg fire extinguisher or other suitable extinguishant agent, when carrying small amounts (less than 15kg) of clinical waste as part of their duties (see ref),subject to the following conditions:

- clinical waste or used medical devices are packaged in accordance with clause 7.3.2.6 of ADR 2023
- the total weight is less than or equal to 15 kg while recognising that more than one patient may be treated before the waste is taken for disposal
- the vehicle used for carriage is a private car or car derived van that is a class M1 vehicle
- clinical waste or used medical devices should only be carried from the site of any treatment for disposal or decontamination where no alternative arrangement is possible.

Appendix A Category A and B Infectious Substances

A.1 While it is highly unlikely that Decontamination Units will encounter highly infectious materials classified as Category A in the International Carriage of Dangerous Goods by Road (ADR) 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 Health and Safety Executive (HSE).

A.2 Category A substances are defined as:

"an infectious substance which is carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease in otherwise healthy humans or animals. This definition is supplemented by an indicative list of pathogens, which include HIV and hepatitis B viruses (but not hepatitis C virus), when in the form of cultures but does not encompass specimens from patients suspected of having these infections."

A.3 Category B substances are defined as: any infectious substance that does not meet the criteria for inclusion in category A. The proper shipping name (PSN) for items assigned to UN 3373 should be "BIOLOGICAL SUBSTANCE, CATEGORY B" (see ref 24). This would include specimens from patients with known or suspected infections.

A.4 Samples of materials such as blood, tissue, excreta, secreta, collected from humans or animals are considered, as a minimum, Category B infectious substances. Clinical or medical waste that contain Category B infectious substances (with the exception of cultures), or that have a low probability of containing infectious substances, is assigned to UN 3291and should be transported in accordance with Packing Instruction 650.

A.5 While exemptions can apply to some human specimens known not to contain pathogens due to testing or inactivation, it is not always possible to determine if used medical devices contaminated with blood or human tissue are free from pathogens. Therefore, this guidance recommends that where the status of the substance is unknown all such items should be considered as Category B infectious substances. This will prevent inadvertent non-compliance with health and safety regulations which could result in legal action (see reference15, 16 and 17).

Abbreviations

ADN: European Agreement concerning the International CDGs by Inland Waterway

ADR: International Carriage of Dangerous Goods by Road

AN(DG)R: Air Navigation (Dangerous Goods) Regulation

CDGUTPE: Carriage of Dangerous Goods and Use of Transportable Pressure Equipment

CDU: Central Decontamination Unit

COSHH: Control of Substances Hazardous to Health

COTIF: Convention concerning International Carriage by Rail

DfT: Department for Transport

DGSA: Dangerous Goods Safety Adviser

DoT: Department for Transport

DVLA: Driver and Vehicle Licensing Agency

EDU: Endoscope Decontamination Units

HFS: Health Facilities Scotland

HSE: Health and Safety Executive

IBC: Intermediate Bulk Container

ICAO: International Civil Aviation Organisation

IMDG: International Maritime Dangerous Goods

LDU: Local Decontamination Unit

MCA: Maritime and Coastguard Agency

NOS: Not Otherwise Specified

PG: Packing Group

PSN: Proper Shipping Name

RMDS: Reusable Medical Devices

RID: Regulation concerning the ADR by Rail

RMD: Reusable Medical Devices

SHTM: Scottish Health Technical Memorandum

SHTN: Scottish Health Technical Note

UKAS: United Kingdom Accreditation Service

UNECE: United Nations Economic Commission for Europe

VCA: Vehicle Certification Agency

VTC: Vocational Training Certificate

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.

Clinical waste - any waste which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, pharmaceuticals, dressings, sharps and so on.

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.

Hazard class - nine divisions of dangerous goods determined by their primary risk.

Infectious substance - substances which are known or are reasonably expected to contain pathogens.

Label - a diamond shape indicating a UN hazard class.

Limited quantities - a method of carrying dangerous goods that are exempted from most legislation by virtue of the small volumes in each package.

Packing group (PG) - 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.

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.

References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current version of these references.

1 **The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) (EU Exit) Regulations 2020** (UK Statutory Instruments 2020 No. 1111. The National Archives Transporting dangerous goods (see GOV.UK website)

2 ADR 2023 - Agreement concerning the International Carriage of Dangerous Goods by Road. ADR applicable as from 1 January 2023 UNECE.

3 **The European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) (2009)** the Annex to the Regulation concerning the International Carriage of Dangerous Goods by Rail (RID) which forms Appendix C to the Convention concerning International Carriage by Rail ("COTIF") (Current Edition: 2009)

4 **The Regulations annexed to the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway** ("ADN") (Current edition: 2009). Directive 2002/50/EC of 6 June 2002 (O.J. No. L149, 7.6.2002, p. 28)

5 International Maritime Dangerous Goods (IMDG) Code, 2022 Edition, 1 January 2024.

6 The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations, 1997, Department for Transport.

7 Air Navigation (Dangerous Goods) Regulations (AN(DG)Rs), 2002, UK Civil Aviation Authority.

8 **Department for Transport (DfT) - Security Guidance on the Carriage of Dangerous Goods by Road and Rail Regulations** 5, 7 and 8 of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulation (CDGUTPE) 2009 as amended 2020.

9 **Carriage of dangerous goods: approved derogations, transitional provisions and exceptions**, Updated 30 June 2023 Road Derogations - Road derogation 17 (RO-a-UK-10) DfT, Transporting dangerous goods (see GOV.UK website)

10 **Scottish Health Technical Note (SHTN) 03 - 01** NHSScotland Waste Management Guidance Version 7.0: 2023

11 **WHO Guidance on regulations for the transport of infectious substances** 2021-2022 applicable as from 1 January 2021

12 **Management of reusable surgical instruments during transportation, storage and after clinical use** -GUID 5010 Part B - Operational guidance 2014 Health Facilities Scotland (HFS).

13 The Control of Substances Hazardous to Health (COSSH) Regulations 2002 Health and Safety Executive (HSE)

14 Department of Transport (DfT) Guidance note 17/2012[rev7]) Transport of Infectious Substances UN2814, UN2900 and UN3373

15 Dangerous Goods Packaging - with the exception of medical devices and specimens known to be contaminated with Category A infectious organisms

16 Infectious Substances, Clinical Waste and Diagnostic specimens - HSE (accessed December 7, 2023)

17 **UN Amendment to 2.6.3.2 of the Model Regulations** Rev 23 - classification of infectious substances (WHO) 2024

18 Carriage of Dangerous Goods Manual - HSE

19 **International Civil Aviation Organization (ICAO)** - Technical Instructions for the Safe Transport of Dangerous Goods by Air 2023-2024 (Doc 9284).

20 **Scottish Health Planning Note (SHPN)13 part 1** - Decontamination Facilities: Central Decontamination Unit: 2011. HFS.

21 Health and Safety at Work etc Act 1974 - The National Archives

22 The Personal Protective Equipment at Work (Amendment) Regulations 2022. The National Archives.

23 Management of Health and Safety at Work Regulations (1999). National Archives

24 The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 ("CDG 2009"), 1 July 2009, Department for Transport. The National Archives.