Transporting Patient Specimens

Enhancing Health & Safety in RCSI

RCSI DEVELOPING HEALTHCARE LEADERS WHO MAKE A DIFFERENCE WORLDWIDE

Patient specimens are transported by public road to and from Royal College of Surgeons facilities for diagnostic purposes. When the specimens are transported by public road they must be packaged in accordance with packing instruction P650 of the ADR Road Transport Regulations.

The purpose of this SOP is to provide a standardised methodology for the performance of this task that complies with packing instruction p650 of the ADR Road Transport Regulations for the transport of dangerous goods.

This SOP applies to all employees of RCSI involved in the packaging and transport of patient specimens by public road.

References:

- ADR European Agreement concerning the International Carriage of Dangerous Goods by Road 2015.
- Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment (S.I. No. 349 of 2011)

Definitions:

- *"Patient specimens"* are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being carried for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.
- *"Infectious substances"* are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

Procedure:

RCSI (as the sender/consignor) is responsible for the packaging and transporting of patient specimens in accordance with the European Agreement concerning the International Carriage of Dangerous Goods by Road regulations 2015. The packaging must meet various specifications to minimise the risk of infection to those who may come in contact with the specimens and also to ensure that the specimens arrive in tact.

Specimens sent by road must be packaged correctly according to the following guidelines:

Primary Receptacle:
The specimen must be enclosed in a primary receptacle. The sender must ensure that the container is appropriate for the purpose, is properly closed and that it is not externally contaminated. The container must be leak-proof for liquids and Sift-proof for solids.

Secondary Container:
The primary receptacle must be placed in an approved secondary watertight container which is leak-proof. Absorbent material, sufficient to absorb the entire liquid contents must be placed between the primary and secondary container. Either the primary or secondary packaging shall be leak proof at a pressure difference of 95kPa.

Outer Packaging:
The secondary container must be placed in an outer container with minimum dimensions on two sides of 100mm x 100mm. Cushioning material shall be placed between the secondary and outer container. Note: The secondary container or outer package must be rigid.

Labelling of Outer Package:
The outer packaging must be marked clearly as per Figure 1 below. The minimum size of the diamond on the label shall be 50mm x 50mm. At least one surface of the outer packaging shall have a minimum dimension of 100mm x100mm.

Figure 1: Mandatory Label for outer package

Packaging Instructions for Patient Specimens:
Patient Specimens when transported by road must be packaged in accordance with packing instruction P650 of the ADR European Agreement concerning the International Carriage of Dangerous Goods by Road Regulations 2015. The following is the recommended method of preparing a sample for transport by road.

Step 1: Primary Receptacle:
- The patient specimen must be enclosed in a primary receptacle e.g. blood tube, urine container.
- The sender must ensure that the primary receptacle is appropriate for the purpose and is leak-proof for liquids and sift-proof for solids.

- The sender must ensure that the primary receptacle is properly closed and that it is not externally contaminated.

Figure 2: Primary Receptacle

Step 2: Secondary Container:

- The primary receptacle i.e. blood tube must be placed in a secondary container which is watertight and is leak-proof.
- Either the primary of secondary packaging shall be leak-proof at a pressure difference of 95kPa (0.95bar)

Figure 3: Example of a Secondary Container – A plastic leak-proof mailing bag

Figure 4: Example of a Secondary Container - A round leak-proof mailing container

*Figure 5: Absorbent material **must be placed** between the primary and secondary container*

Step 3: Outer Packaging:

- The secondary mailing container must be placed in an outer packaging.
- At least one surface of the outer packaging shall have a minimum dimension of 100mm x 100mm.
- Cushioning must exist between the secondary and outer container.

Figure 6: Either the secondary container or outer packaging must be rigid

Step 4: Marking of Outer Package:
The outer package must be labelled as per Figure 1. In addition the label must identify the name and address of the sender and the name and address of the hospital receiving the specimen.

Step 5: Transport of Specimen:
Once the specimens are packaged and labelled according to the above guidelines they can be collected by the courier company or transported by road by staff using private or service vehicles.

Transportation of large quantities of specimens:
The following are the guidelines for the transport of large quantities of specimens:

Large boxes can be used for the delivery of large numbers of specimens via couriers. These boxes must be made of smooth impervious material such as plastic or metal, which can be easily disinfected or cleaned. The boxes must be:

- secured with a fastenable lid and retain liquids in the event of a spillage
- clearly labelled with “Biological Substance, Category B”

The label must also identify the sender including relevant telephone numbers to be contacted in case of an emergency.

Figure 7: Sample container for larger quantities

Important Notes:
The packaging’s used in the illustrations of this procedure are given as examples. Other types of packaging’s may be used so long as it meets the requirements of packing Instruction P650 of the ADR regulations.

Placing specimens in an envelope does not constitute packaging which is in compliance with the regulations.

A substantial fine may be imposed on the **sender/consignor** for not packaging and labelling the specimens according to the ADR road transport regulations.

Appendices:

P650	PACKING INSTRUCTION	P650

This packing instruction applies to UN No. 3373

(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including transhipment between vehicles or containers and between vehicles or containers and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.

(2) The Packaging shall consist of three components:

(a) a primary receptacle
(b) a secondary packaging; and
(c) an outer packaging.

Of which either the secondary or the outer packaging shall be rigid.

(3) Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of carriage, they cannot break, be punctured of leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packagings with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.

(4) For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at angle of 45° (diamond-shaped) with minimum dimensions of 50mm by 50mm; the width of the line shall be at least 2mm and the letters and numbers shall be at least 6mm high. The proper shipping name "BIOLOGICAL SUBSTANCE, CATERGORY B" in letters at least 6mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.

(5) At least one surface of the outer packaging shall have a minimum dimension of 100mm x100mm.

(6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3 as specified in 6.3.5.2 at a height of 1.2m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.

(7) For liquid substances:

(a) The primary receptacle(s) shall be leakproof;
(b) The secondary packaging shall be leakproof;
(c) If multiple fragile primary receptacles are placed in a single secondary packaging. They shall be either individually wrapped or separated to prevent contact between them.
(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

(8) For solid substances:

(a) The primary receptacle(s) shall be siftproof;
(b) The secondary packaging shall be siftproof;
(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
(d) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during carriage then a packaging suitable for liquids, including absorbent materials, shall be used.

(9) Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

(a) When dry ice or liquid nitrogen is used as a coolant, the requirements of 5.5.3 shall apply. When used, ice shall be placed outside the secondary packaging or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packaging in the original position. If ice is used, the outside packaging or overpack shall be leakproof.
(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

(10) When packages are placed in an overpack, the package markings required by this packing instructions shall either be clearly visible or be reproduced on the outside of the overpack.

(11) Infectious substances assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in ADR.

(12) Clear instructions on filling and closing such packages shall be provided by packaging manufactures and subsequent distributors to the consignor or to the person who prepares the package (e.g.

patient) to enable the package to be correctly prepared for carriage.

(13) Other dangerous goods shall not be packed in the same packaging as Class 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements of ADR need be met.

(14) If any substances have leaked and been spilled in a vehicle or container, it may not be reused until after it has been thoroughly cleaned and, if necessary, disinfected or decontaminated. Any other goods and articles carried in the same vehicle or container shall be examined for possible contamination.

Additional requirement:
Alternative packagings for the carriage of animal material may be authorized by the competent authority of the country of origin* in accordance with the provisions of 4.1.8.7.

*If the country of origin is not a Contracting Party to ADR, the competent authority of the first Contracting Party to the ADR reached by the consignment.