The transfer of relevant material into and out of Newcastle University for storage or use in research

NJRO-TISS-SOP-002

Contents

1. Background/Introduction

Newcastle University holds a research sector Human Tissue Authority licence (ref. 12534). This licence authorises the storage of "relevant material" (material, other than gametes, that consists of, or includes human cells) which has come from a human body for research in connection with disorders, or the functioning, of the human body. Material is stored in Newcastle University on behalf of internal researchers and for external clients/collaborators.

If relevant material is to be transferred between establishments consideration must be given to minimising the likelihood of theft, damage or loss during transport. Some form of formal arrangement, for example, as part of a Material Transfer Agreement (MTA) should define how the human tissue is preserved, any potential contamination risks associated with it and who is responsible for disposal if applicable.

Documented policies and procedures must:

- Clearly assign responsibilities to the senders and recipients of material
- Protect the quality and integrity of human material during transport and delivery to a destination
- Protect the safety of all personnel coming into contact with the material.
- Include a risk assessment for transportation, including a system to ensure that traceability of relevant material is maintained during transportation
- Consider environmental controls to avoid potential contamination and ensure safety. Staff must be provided with appropriate protective equipment/facilities and procedures that minimise risk.
- Maintain an audit trail which details when and where the bodies/body parts were put, when the bodies/body parts were transferred and to whom.
- Retain records of transportation and delivery including transfer agreements with recipients of relevant material.

In addition, in accordance with the terms and conditions of ethical approval granted to a research study or research tissue bank, a supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with the HTA Codes of Practice, the terms of the ethical approval and any other conditions required by the study/bank.

The Human Tissue Authority do not specify or endorse any particular format for MTAs; however, a number of template agreements are publicly available and can be adapted to suit individual circumstances.

This SOP details the procedure adopted at Newcastle University when sending or receiving material classed as “relevant material” under the Human Tissue Act, to and from Newcastle University premises.

2. Purpose

The purpose of this SOP is to provide staff working under the Human Tissue Authority research licence at Newcastle University with information on the procedures to be followed when transferring relevant material in to, and out of Newcastle University premises.

3. Scope of Document

This SOP applies to any personnel working under the Newcastle University Human Tissue Authority research licence. This includes Persons Designated, Chief Investigators of National Research Ethics Service (NRES) Research Ethics Committee (REC) approved research tissue banks, and local collaborators (e.g. Principal Investigators, laboratory staff, tissue collection centres).

This SOP does not apply to

- The transfer of relevant material under the Human Tissue Act between Newcastle Hospitals and Newcastle University. Due to the close partnership between the two organisations, this is covered separately under NJRO-TISS-SOP-001.
- Material out-with the scope of the Human Tissue Act (i.e. non-relevant material such as DNA); however it is good practice to manage all human material according to the same procedure.
- The transfer of human material for purposes other than research (e.g. post-mortem, anatomy, human application)
- Internal transfers of material (i.e. within Newcastle University premises)

4. Definitions

DI	Designated Individual
HTA	Human Tissue Act
MTA	Material Transfer Agreement - A legal contract that governs the transfer/exchange of tangible research material between two organisations, where the researcher wishes to use the material for their own research purposes. This legal document is important as it clearly defines the rights of the parties in respect

	to scope of use of material, confidentiality, publication, and ownership of Intellectual Property. In addition, in compliance with the Human Tissue Act and associated Codes of Practice, this aims to protect the material from theft, damage or loss, and clearly establish the terms of the transfer.
NJRO	Newcastle Joint Research Office
Non-relevant material	Material out-with the scope of the Human Tissue Act
NRES	National Research Ethics Service
NuTH	Newcastle upon Tyne Hospitals NHS Foundation Trust
PD	Persons Designated
REC	Research Ethics Committee
Relevant Material	Material within the scope of the Human Tissue Act, and defined as "Material other than gametes, which consists of or includes human cells"
Research	A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.
R&D	Research and Development
SOP	Standard Operating Procedure

5. Roles & Responsibilities

It is the responsibility of

- All personnel responsible for sending, or the receipt of relevant material under the Human Tissue Act (2004) to follow the procedures set out in this SOP. It is the responsibility of all recipients of tissue to ensure that they have the appropriate

ethical approval and consent in place to store and use samples, and samples are stored in accordance with the regulations.

- Any personnel sending relevant material to ensure appropriate due diligence is completed on the sample recipient, and they have the appropriate permissions/approvals and licensing in place.

- The NJRO Quality Management team to audit compliance with these procedures.

6. Procedures

6.1. Material Transfer Agreements (MTAs)

A Material Transfer Agreement (MTA) is a contract that governs the transfer of research materials (human and non-human e.g. human tissue or assays) between two organizations when the recipient intends to use them for their own research purposes. They define the rights of the parties in respect to the scope of use of the material, confidentiality, publication, and ownership of Intellectual Property. MTAs usually do not include payment for the material, other than the reimbursement of transport costs.

All MTAs at Newcastle University are managed by the Legal Services. It is a Newcastle University policy that all material moving into or out of the University must be covered by an MTA. The only exception is material coming in from Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH). In this instance, transfers are covered by the SLA in place between the two organisations (see NJRO-TISS-SOP-01).

At Newcastle University, MTAs are used in two situations:

1. **Incoming MTA -** For material coming INTO Newcastle University from an external organisation, *other than* Newcastle upon Tyne NHS Foundation Trust. See section **6.1.1 and figure 1**

2. **Outgoing MTA -** For material going OUT of Newcastle University to an external organisation, *other than* Newcastle upon Tyne NHS Foundation Trust. See section **6.1.2 and figure 1**

In some instances, it may be believed by the sending or receiving institution that the terms of the transfer of a material may be covered by another formal agreement e.g. a collaboration agreement, tri-partite agreement or protocol. In these instances, researchers must be

confident that the arrangement considers the minimisation of the likelihood of theft, damage or loss during transport, and should define how the human tissue is preserved, and any potential contamination risks associated with it and who is responsible for disposal if applicable. For further advice, please contact Legal Services (legal.aservices@ncl.ac.uk).

6.1.1. Incoming MTA

If you are **receiving Material from another organisation**, the providing organisation would usually issue a Material Transfer Agreement (MTA). All incoming MTAs must be reviewed and authorised by Legal Services.

If you are a Newcastle University employee undertaking research using the material on University premises please complete and submit a Legal Request for Material Transfer Agreement (MTA) - Incoming , uploading the MTA document if available. The MTA will be reviewed by an authorised member of Legal Services and signed off, if the terms are acceptable. If there are any terms within the MTA that are not suitable we will liaise with the provider of the material to reach an agreeable final document.

If the research project is registered with the Newcastle Hospital's Trust R&D, please send the proposed MTA to the generic R&D email address: nuth.genericqueries@nhs.net.

Incoming MTAs must clearly state if the material is going to be used in a research project, or stored under the University's HTA licence for use in future research. Material requiring storage under the licence may only be stored in approved storage locations, overseen by a named Person Designated. For further information, please contact HumanTissueResearch@ncl.ac.uk.

Once the terms have been agreed, Legal Services will send the Newcastle University researcher a copy of the signed MTA, and the transfer may commence – see **section 6.3.**

6.1.2. Outgoing MTA

If you are a Newcastle University employee and wish to **transfer some proprietary research material to another organisation**, please complete and submit a Legal Request for Material Transfer Agreement (MTA) - Outgoing. A suitable MTA will be drafted by an authorised member of Legal Services and they will liaise with the recipient organisation to agree a suitable MTA before the material is released.

For research tissue banks which use a large number of MTAs, a standard template may be provided to the tissue bank that can be completed independently of Legal Services by the tissue bank. In this instance, the tissue bank will be responsible for completing the editable fields in the document, including the recipient organisation, material to be sent, etc. The

tissue bank will then be responsible for sending this MTA to the recipient organisation for signature by email, copying in Legal Services. If there are any terms within the MTA that are not suitable, Legal Services will liaise with the recipient of the material to reach an agreeable final document. The MTA will be signed by the recipient organisation and Legal Services. Legal Services will be responsible for logging the MTA on NUProjects.

Once fully executed, Legal Services will send the Newcastle University researcher a copy of the signed MTA, and the transfer may commence**.**

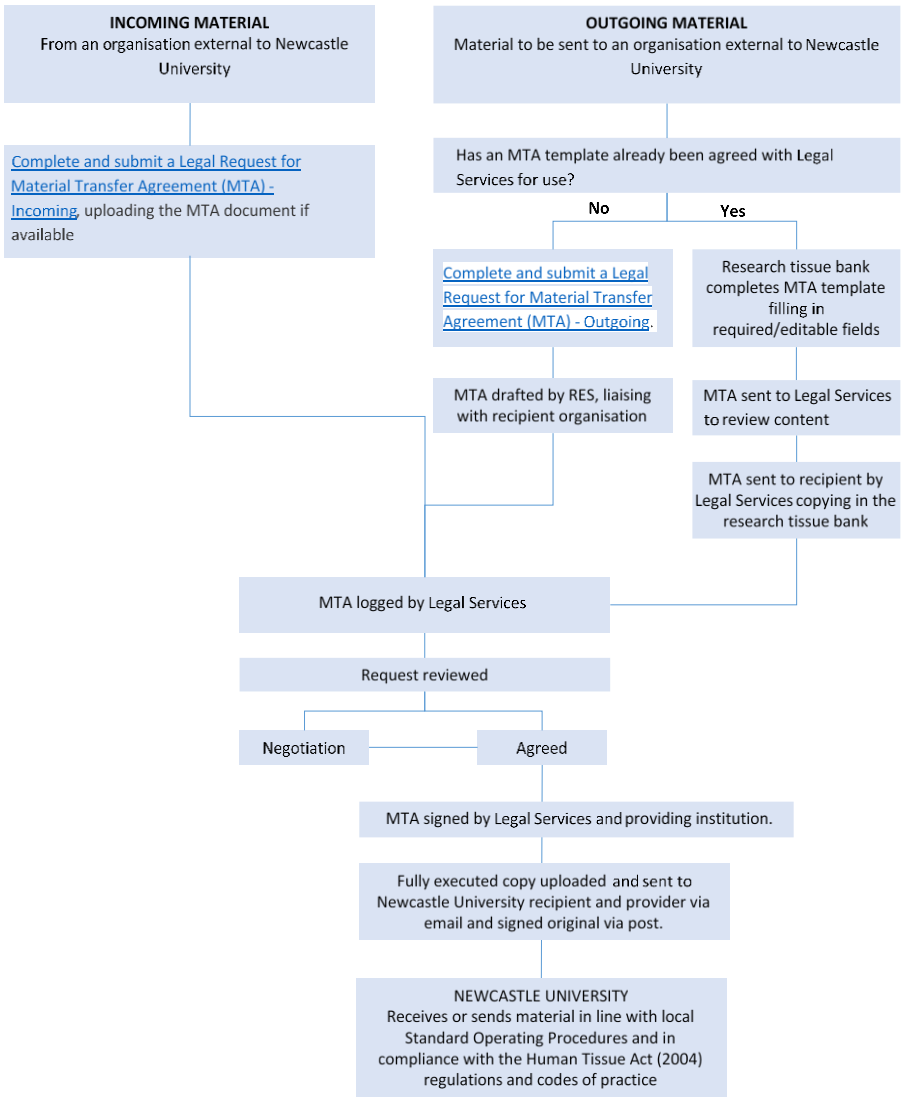

Figure 1: Transfer of materials under a Material Transfer Agreement (MTA) at Newcastle University

6.2. Sample transportation and safety

Once a transfer agreement has been formally agreed, the material can be transported into, or out of, Newcastle University. Before any material is transferred between institutions a risk assessment should be conducted for transportation by the person responsible for arranging the transfer, including consideration of maintaining the integrity and traceability of the material during transportation, and safety (e.g. contamination, protective equipment and facilities to minimise risk).

Material which poses a biological hazard, such as human tissue, is required by law to be transported in a safe and contained manner to prevent contamination or exposure to infectious substances.

Researchers interested in transporting biological materials should contact their Schools Biological Safety Supervisor or School Safety Officer in the first instance and refer to the Newcastle University Safety Office Website:

http://safety.ncl.ac.uk/transportofbiologicalhazards.aspx.

A summary of the safety requirements is provided below however all staff should refer to the Safety Office website for full information.

There are 2 categories of infectious biological agents:

Category A	An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease to humans or animals.
	Classified as code: **UN 2814**
	For example: Poliovirus or rabies virus (cultures only). A full list of UN2814 materials can be found on the USO website under Biotransport tab. Only maternail belonging to Hazard Groups 1-3 may enter the University, material from Hazard Group 4 are not permitted within the University.
	Only personnel who have attended approved IATA/ICAO course and passed examinations can handle and package these substances. Staff who do not hold or do not wish to obtain accreditation are advised to use an approved Category A courier that will package samples on your behalf
Category B	Any infectious substance that does not meet the criteria for inclusion in Category A.
	Classified as code: **UN 3373**
	Only personnel who are aware of the regulations and correct packaging requirements and have completed relevant forms for transportation can handle and package these substances.

As nearly all the relevant material sent out of, or brought into the University falls in to "Category B" the transport requirements for Category B material is provided below in section 6.3.1. Exemptions to these rules may apply are summarised in section 6.3.2.

6.2.1. Transport of Category B Material

For category B (UN 3373) material only approved/tested packaging must be used in accordance with International Air Transport Association (IATA) packaging instruction 650, which can be found on the following website:

https://www.iata.org/whatwedo/cargo/dgr/Documents/DGR-60-EN-PI650.pdf

A copy of this packing instruction is also attached in Appendix 1.

The Royal Mail/Parcel Force may be used for Category B Biological Substances only, and NOT for category A materials. A guidance document for the transport of infection substances can be found at the following link:

https://www.royalmail.com/sites/default/files/Guidance-Document-Infectious-Substances-171012.pdf

A figure taken from this guidance document demonstrating how Category B material should be packaged is found in Appendix 1 of this document.

6.2.2. Biological transport exemptions

An element of professional clinical judgment is required to determine if a substance is exempt from the transport arrangements set out in 6.3.1, for example, in cases where there is minimal likelihood of pathogens.

Examples of biological materials which are exempt from these transport arrangements include:

- Non-pathogenic micro-organisms or neutralized / inactivated pathogens
- Environmental samples, including “harmless” food and water samples
- Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests
- Blood or blood components collected for the purposes of transfusion
- Patient specimens for which there is minimal likelihood that pathogens are present

In these instances materials should be transported in packaging which will prevent any leakage and which is marked with the words “Exempt human specimen”.

A figure taken from the IATA infections substances guidance document demonstrating the packaging and marking of exempt material is found in Appendix 2 of this document.

6.3. Sample tracking

To ensure an audit trail is maintained for any material being transferred between two institutions, local sample tracking records (e.g., Achiever) should be updated with the details of when and where the materials were put, when the materials were transferred to and to whom.

Records of transportation and delivery should also be retained as evidence (e.g., waybill numbers, emails confirming satisfactory receipt by the other institution). In addition, for imported/exported tissue, documentation of the consignment should be retained for at least 5 years after disposal of the last part included in the consignment.

When a transfer agreement expires any remaining material should be managed in accordance with the terms agreed in the original transfer agreement.

6.4. Sample receipt

Samples should only be accepted into a laboratory if they have been packaged and labelled appropriately. Therefore, all collaborators should be informed that they must send packages in accordance with UN3373 regulations.

All personnel should be provided with suitable personal protective equipment (e.g., gloves, lab coats, safety cabinets) and be suitably trained to handle the material. Where appropriate, risk assessments should be in place for transportation, including a system to ensure that traceability of relevant material is maintained during transportation, and suitable safety measures are in place when receiving samples.

In instances where a package is not clearly labelled or the risks are unknown, the packages should not be opened and should be placed in a quarantine area and more information sought. If in doubt, researchers should contact the University's Occupational Health and Safety Services office for advice.

Materials should only be used in accordance with the terms and conditions set out in the transfer agreement (where appropriate) and in accordance with terms and conditions of ethical approval and stored appropriately.

7. References

Human Tissue Authority website: www.hta.gov.uk

The International Air Transport Association (IATA) http://www.iata.org

The Royal Mail Guidance for Infectious Substances

https://www.royalmail.com/sites/default/files/Guidance-Document-Infectious-Substances-171012.pdf

8. Appendices

8.1. Appendix 1 - International Air Transport Association (IATA) Packing Instruction 650

For the most up-to-date version of this instruction please refer to http://www.iata.org

IATA

Packing

PACKING INSTRUCTION 650

STATE VARIATIONS: BHG-02, CAG-05, DQG-03, GBG-05, GHG-02, IDG-02, VCG-04

OPERATOR VARIATIONS: 4C-04, 4M-04, 5X-02, AM-06/10, AR-02, AS-08, BR-14, BZ-07, CM-05, E9-03, FX-04, G3-02, IP-03, JJ-04, KC-08, KE-06, L7-04, LA-07, LH-05, LP-04, LU-04, M3-04, M7-04, MS-06, OS-05, OU-12, PX-08, SV-12, TN-05, UC-04, UU-05, WR-03, WS-03, XG-05, XL-04, XQ-05

This instruction applies to UN 3373 on passenger and cargo aircraft and Cargo Aircraft Only.

General Requirements

The packagings must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packagings must be constructed and closed so as to prevent any loss of contents that might be caused under normal conditions of transport, by vibration, or by changes in temperature, humidity or pressure.

The packaging must consist of three components:

(a) a primary receptacle(s);

(b) a secondary packaging; and

(c) a rigid outer packaging.

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

Packages must be prepared as follows:

(a) For liquid substances:

1. The primary receptacle(s) must be leakproof and must not contain more than 1 L;
2. The secondary packaging must be leakproof;
3. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
4. Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material, such as cotton wool, must be in sufficient quantity 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;
5. △ The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure of 95 kPa.
6. The outer packaging must not contain more than 4 L. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

Note:
The capability of a packaging to withstand an internal pressure without leakage that produces the specified pressure differential should be determined by testing samples of primary receptacles or secondary packagings. Pressure differential is the difference between the pressure exerted on the inside of the receptacle or packaging and the pressure on the outside. The appropriate test method should be selected based on receptacle or packaging type. Acceptable test methods include any method that produces the required pressure differential between the inside and outside of a primary receptacle or a secondary packaging. The test may be conducted using internal hydraulic or pneumatic pressure (gauge) or external vacuum test methods. Internal hydraulic or pneumatic pressure can be applied in most cases as the required pressure differential can be achieved under

PACKING INSTRUCTION 650 *(continued)*

most circumstances. An external vacuum test is not acceptable if the specified pressure differential is not achieved and maintained. The external vacuum test is a generally acceptable method for rigid receptacles and packagings but is not normally acceptable for:

- flexible receptacles and flexible packagings;
- receptacles and packagings filled and closed under an absolute atmospheric pressure lower than 95 kPa.

(b) For solid substances:

1. The primary receptacle(s) must be siftproof and must not exceed the outer packaging weight limit;
2. The secondary packaging must be siftproof;
3. If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them;
4. Except for packages containing body parts, organs or whole bodies, the outer packaging must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
5. If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, must be used.

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An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.

The completed package must be capable of successfully passing the drop test described in 6.5.4.4 as specified in 6.5.4.2 except that the height of the drop must not be less than 1.2 m. Following the appropriate drop sequence, there must be no leakage from the primary receptacle(s) which must remain protected by absorbent material, when required, in the secondary packaging.

For transport, the mark illustrated below must be displayed on the external surface of the outer packaging on a background of a contrasting colour and must be clearly visible and legible. The mark must be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm, the width of the line must be at least 2 mm and the letters and numbers must be at least 6 mm high. The proper shipping name "Biological Substance, Category B" in letters at least 6 mm high must be marked on the outer packaging adjacent to the diamond-shaped mark.

Unless all package marks are clearly visible, the following conditions apply when packages are placed in an overpack:

△
- the overpack must be marked with the word "Overpack" in lettering at least 12 mm high; and
- the package marks must be reproduced on the outside of the overpack.

A Shipper's Declaration for Dangerous Goods is not required.

Alternative packagings for the transport of animal material may be authorized by the competent authority in accordance with the provisions in 5.0.6.7.

IATA

Packing

PACKING INSTRUCTION 650 *(continued)*

Specific Requirements

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

- When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of these Regulations must be met. When used, ice or dry ice must be placed outside the secondary packagings or in the outer packaging or an overpack. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or overpack must be leakproof. If dry ice is used, the packaging must be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packagings.
- The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures, which could result if refrigeration were to be lost.

Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement of these Regulations except for the following:

(a) the name and address of the shipper and of the consignee must be provided on each package;

(b) the name and telephone number of a person responsible must be provided on the air waybill or on the package;

(c) the classification must be in accordance to 3.6.2;

(d) the incident reporting requirements in 9.6.1 must be met; and

(e) the inspection for damage or leakage requirements in 9.4.1 and 9.4.2.

Note:
When the shipper or consignee is also the 'person responsible' as referred to in b) above, the name and address need be marked only once in order to satisfy the name and address marking provisions in both a) and b), above.

Passengers and crew members are prohibited from transporting infectious substances as or in carry-on baggage, checked baggage or on their person.

If an Air Waybill is used, the "Nature and Quantity of Goods" box must show "UN 3373", the text "BIOLOGICAL SUBSTANCE, CATEGORY B" and the number of packages.

Clear instructions on filling and closing such packages must be provided by packaging manufacturers and subsequent distributors to the shipper or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.

Other dangerous goods must not be packed in the same packaging as Division 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 30 mL or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances provided these substances meet the requirements of 2.6. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction, no other requirements in these Regulations need be met.

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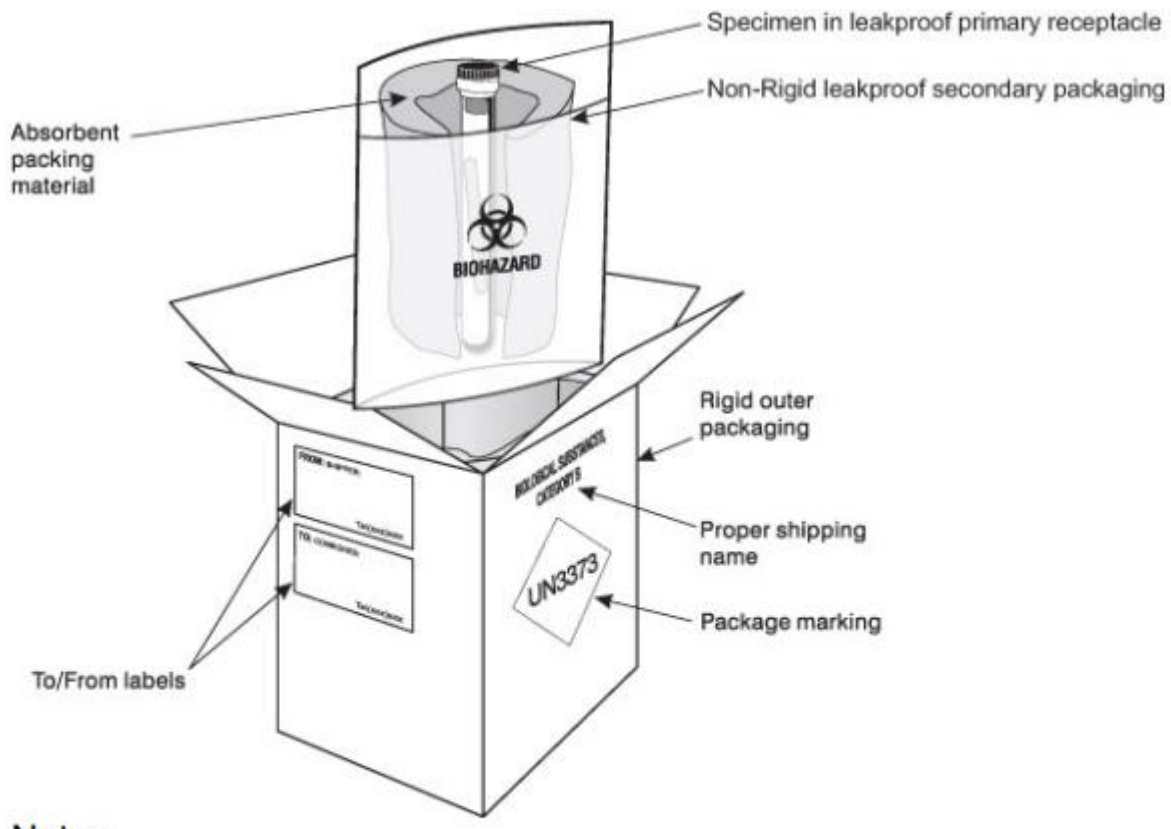
8.2. Appendix 2 – Packaging and Marking

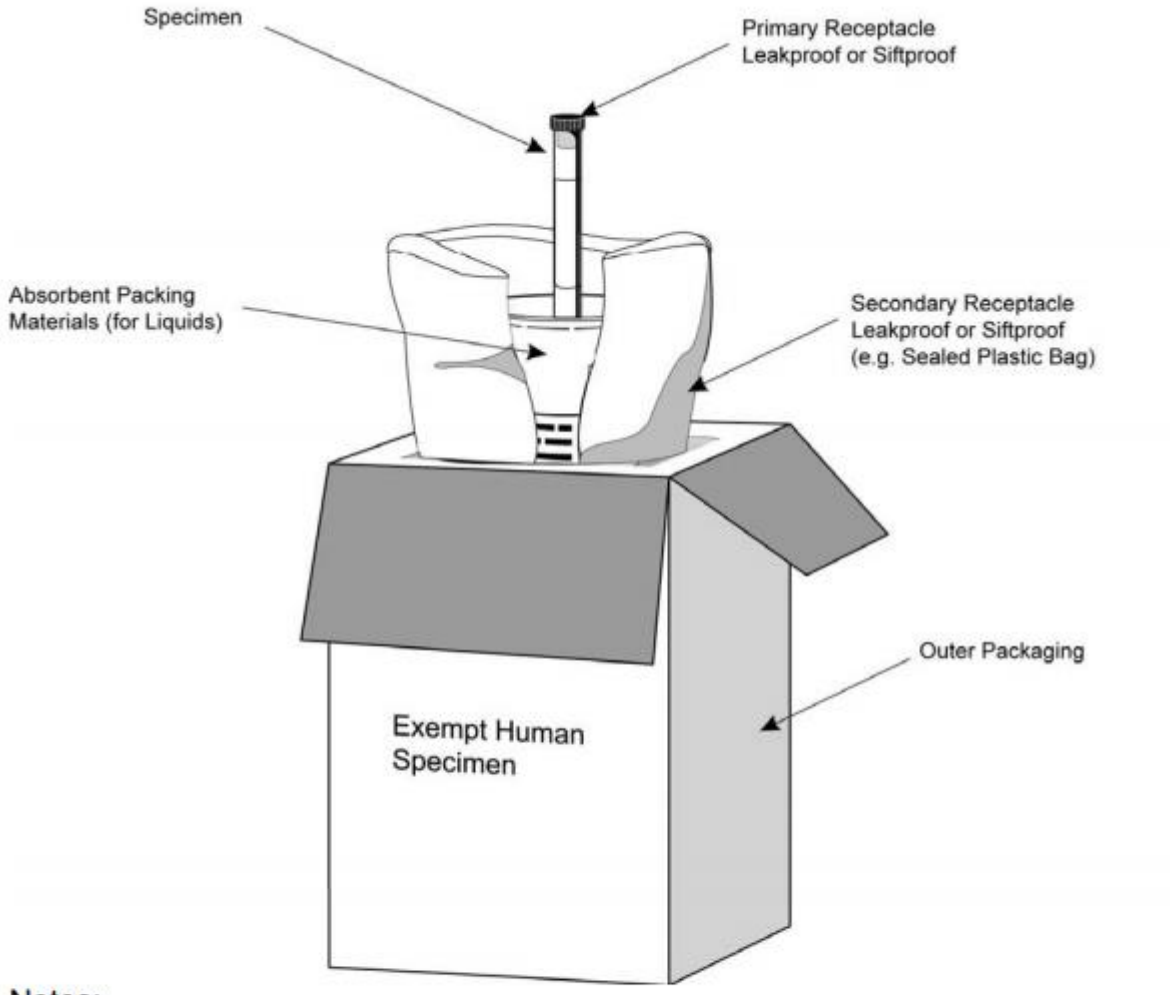
Example of Packing and Marking for Category B Infectious Substances



Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa.

Example of Packing and Marking for Exempt Specimens



Notes:

1. At least one surface of the outer packaging must have a minimum dimension of 100 mm x 100 mm;
2. The outer packaging must be of adequate strength for its capacity, mass and intended use.

Taken from IATA infectious substances guidance document

http://www.royalmail.com/sites/default/files/Guidance-Document-Infectious-Substances-171012.pdf