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Biotechnology — General requirements for transportation of cells for therapeutic use

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Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Cells for therapeutic use provide potential cures for the most challenging disease conditions. However, in contrast to the unprecedented clinical benefits, managing the production and logistics of cells for therapeutic use proves to be challenging. Not only the cost is exceedingly high to produce and transport these products, the concerns over product safety and efficacy due to potential manufacturing or transportation deficiencies have started mounting as more products are being developed and tested.

The cell therapy workflow begins with collection of cells (including tissues). With autologous cells for therapeutic use, cells are collected from patients in the clinical setting before shipping to manufacturing sites for processing and production. After manufacturing and testing for release, cells for therapeutic use are transported to clinical sites for administration into patients.

Issues related to cell transportation have been identified in the product workflow. Some of these issues include monitoring and controlling transportation conditions, managing traceability and maintaining chain of custody, and establishing clear expectations and communications between cell product manufacturer and transportation service provider. These issues all have significant impact on cells for therapeutic use quality that can ultimately affect product safety and effectiveness. Therefore, there is a need for standards to ensure cell transportation is appropriately and adequately planned, executed, traced and documented.

This document intends to provide general requirements and points to consider for transportation service providers, clients and senders to ensure cell quality, safety and efficacy during the transportation process.

Application of this document presupposes awareness of applicable legal requirements.

ISO 13022:2012, Annex G contains guidance for transport of human cells.

Biotechnology — General requirements for transportation of cells for therapeutic use

1 Scope

This document specifies general requirements and reviews the points to consider for the transportation of cells for therapeutic use, including storage during transportation.

Transportation starts from the transfer of the packaged cells by the sender to the transportation service provider and ends when the package is delivered to the receiver at its destination.

This document does not apply to transportation of cells within one facility.

This document includes the development of a transportation plan including verification and validation, communication between the client and the transportation service provider, and associated documentation.

This document does not specify particular conditions for transportation such as specification for shipping container, ambient temperature control, etc.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
cells for therapeutic use
product containing cells as the active substance

EXAMPLE Cell therapy medicinal product, tissue engineered product.

Note 1 to entry: For the purpose of this document, “cells” mean human cells and tissues of autologous as well as allogeneic.

Note 2 to entry: For the purpose of this document, this term includes cells collected as starting materials and cultured as intermediate materials.

Note 3 to entry: The expression “therapeutic use” includes clinical research, hospital exception and testing use.

3.2
chain of custody
responsibility for or control of materials as they move through each step of a process

Note 1 to entry: For the purpose of this document, “chain of custody” is the proven path starting from the transfer of the packaged cells from the *sender* (3.11) to the *transportation service provider* (3.13) and ends when the package is received at its destination.

3.3
client
entity requesting cell transportation by contract with *transportation service provider* (3.13)

3.4
document
information and the medium on which it is contained

EXAMPLE Record, specification, procedure document, drawing, report, standard.

Note 1 to entry: The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or combination thereof.

Note 2 to entry: A set of documents, for example specifications and records, is frequently called "documentation".

Note 3 to entry: Some requirements (e.g. the requirement to be readable) relate to all types of documents. However there can be different requirements for specifications (e.g. the requirement to be revision controlled) and for records (e.g. the requirement to be retrievable).

[SOURCE: ISO 9000:2015, 3.8.5]

3.5
documented information
information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the management system, including related processes;

— information created in order for the organization to operate (documentation);

— evidence of results achieved [*records* (3.8)].

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

[SOURCE: ISO 9000:2015, 3.8.6]

3.6
inspection
determination of conformity to specified requirements

[SOURCE: ISO 9000:2015, 3.11.7, modified — Notes to entry have been deleted.]

3.7
receiver
entity that gets *cells for therapeutic use* (3.1) from the *transportation service provider* (3.13)

3.8
record
document (3.4) stating results achieved or providing evidence of activities performed

Note 1 to entry: Records can be used, for example, to formalize *traceability* (3.12) and to provide evidence of *verification* (3.15), preventive action and corrective action.

Note 2 to entry: Generally records need not be under revision control.

[SOURCE: ISO 9000:2015, 3.8.10]

3.9
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.10
risk control
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

[SOURCE: ISO/IEC Guide 63:2019, 3.12]

3.11
sender
entity that hands over *cells for therapeutic use* (3.1) to *transportation service provider* (3.13)

3.12
traceability
ability to trace the history, application or location of an object

Note 1 to entry: When considering a product or a service, traceability can relate to:

— the origin of materials and parts;

— the processing history;

— the distribution and location of the product or service after delivery.

Note 2 to entry: In the field of metrology, the definition in ISO/IEC Guide 99 is the accepted definition.

[SOURCE: ISO 9000:2015, 3.6.13]

3.13
transportation service provider
entity that provides international and domestic transportation service of *cells for therapeutic use* (3.1)

Note 1 to entry: Transportation service provider can outsource the whole or part of cell transportation to external service providers. In that case, some requirements described in this document [e.g. the requirement regarding *documented information* (3.5)] can be met by the activities of external service providers. The activities of external service providers vary according to the agreement between the transportation service provider and external service provider, but its activities are managed by transportation service provider.

3.14
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing *documents* (3.4).

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

3.15
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an *inspection* (3.6) or of other forms of determination such as performing alternative calculations or reviewing *documents* (3.4).

Note 2 to entry: The activities carried out for verification are sometimes called a qualification process.

Note 3 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12]

4 General concepts

Consistent quality in transportation of cells for therapeutic use is enabled by establishing:

a) a cell transportation specification based on appropriate sharing information between the transportation service provider and the client, including:

   1) information provided by the client regarding biosafety of cells for therapeutic use during transportation;

   2) information provided by the client regarding storage/handling conditions to preserve cell quality and ensure the therapeutic cell functions.

      NOTE 1 Cell quality can be ensured by demonstrating that the physical, chemical, biological, or microbiological properties are within an appropriate limit, range, or distribution.

b) an operational procedure for cell transportation supported by risk management, verification and/or validation;

c) organizational requirements for transportation of cells for therapeutic use; including the establishment of an appropriate quality management system, training for personnel assigned to a specific cell transportation process, tracking systems, scheduling systems to ensure appropriate protocols are followed;

d) container and facilities requirements including the secure and access control of the facility, ensuring that cells for therapeutic use are not contaminated or tampered;

e) documentation for all stages of cell transportation that demonstrates chain of custody throughout the transportation cycle, including but not limited to equipment performance, cleaning and equipment-use history;

   NOTE 2 Documentation can be a part of quality management system.

f) a system to record each process of cell transportation.

   NOTE 3 The following are examples of the records associated with cell transportation:

   1) objective measurements (e.g. temperature);

   2) transportation logs (e.g. time, name, commodity and signature);

   3) records of data logger;

   4) visual inspection;

   5) shipping containers;

      — unit type (e.g. dry shipper);

      — qualification (in the case of dry shipper, weight, nitrogen evaporation rate and liquid nitrogen capacity);

      — cleaning and disinfection records.

Items of requirements for transportation of cells for therapeutic use agreed between the transportation service provider and the client should be documented and confirmed in writing by each party that they accept the agreed conditions.

5 Cell transportation specification

5.1 General

A cell transportation specification provides a list of requirements that cover the different procedures of transportation operation.

The transportation service provider conducts transportation in accordance with the cell transportation specification.

5.2 Items specified in the cell transportation specification

5.2.1 General

The transportation service provider determines the cell transportation specification, implementing:

a) information submitted by the client and clarified through communication between the client and the transportation service provider;

b) capability of the cell transportation service provider and its external service providers;

c) risk management.

NOTE Items for which the transportation service provider is not responsible for are excluded from the cell transportation specification unless otherwise agreed by both client and transportation service provider. For example, when the client sets up temperature control containers and forwards it to the transportation service provider, the temperature recorder is excluded from the cell transportation specification. The client is responsible for recording the temperature during transport.

5.2.2 Information reflected in the cell transportation specification

5.2.2.1 General

The transportation service provider shall receive necessary information on cells from the client.

Information provided by the client shall be reflected in the cell transportation specification.

5.2.2.2 Classification information

The client should be aware of applicable classification information concerning the cells and their medium to be transported in.

NOTE Categories of goods for transportation can be subject to regulatory classification.

The transportation service provider should retain this information and implement it into the cell transportation specification.

Information on cell and medium classification can include:

a) infectious substances;

b) genetically modified microorganisms / genetically modified organisms;

c) poisonous and deleterious substances.

NOTE The transportation service provider can use this information to control each reusable shipping container.

5.2.2.3 Storage and handling conditions

The client should determine proper storage and handling conditions, based on the result derived from stability testing on cells by the client, and additional transportation testing when needed.

The transportation service providers should retain this information and implement it into the cell transportation specification.

The following are examples of storage and handling conditions:

a) temperature;

b) necessary precautions (e.g. vibrations, locational and orientational placement, UV light, humidity, etc.);

c) maximum shelf life and expiration dates;

d) segregation of human vs. animal derived products to prevent cross contamination;

e) special security requirements (e.g. tamper evident seals or locking mechanisms preventing unauthorized access to shipper contents).

NOTE In some cases, human and animal derived materials have specific requirements for transportation and storage conditions.

5.2.2.4 Shipping information

The client should provide shipping information on cells to be transported.

The transportation service provider should incorporate this into the cell transportation specification.

The following are examples of shipping information:

a) description of goods (including list of contents, condition of goods, intended use of goods, etc.);

b) price/commercial value (e.g. cost of goods as a basis for customs valuation/insurance purposes);

c) dimension;

d) number of pieces;

e) weight;

f) sender's name and address for domestic shipments plus exporter of record's name, address for international shipments;

g) receiver's name and address for domestic shipments plus importer of record's name, address for international shipments;

h) other available information for international shipment, such as VAT-ID, Customs Reg.-Nr., deferment account, HS or commodity code, and any required import permits based on destination country.

5.2.3 Capability of the cell transportation service provider and its external service provider(s)

5.2.3.1 General

The transportation service provider shall determine its capability and its external service provider's capability and shall implement it into the cell transportation specification.

Capability can include:

a) availability and suitability of transportation means (e.g. vehicle, airplane);

b) control tool (e.g. temperature-controlled containers able to meet and maintain the required temperature requirements for the duration of the shipment);

c) human resources;

d) control of container use (e.g. segregation shipment human derived product from animal derived product);

e) protection tool (e.g. locking mechanisms, tamper evident seals).

5.2.3.2 Temperature

The transportation service provider shall establish a transportation temperature range by specifying either upper and lower temperatures, or both, based on the acceptable temperature range during transportation provided by the client and qualified temperature control container ranges.

The following are examples of transportation temperature ranges:

a) ultra-low temperature: below −150 °C;

b) deep freeze: below −20 °C, −40 °C or −80 °C (depending on specification);

c) in a refrigerator: +2 to +8 °C;

d) cold or cool: +8 to + 15 °C;

e) room temperature: +15 to + 25 °C;

f) human body temperature: +32 to +38 °C.

NOTE The acceptable transportation temperature range provided by the client can be different from the temperature specified by storage conditions (see 5.2.2.3) of cells for therapeutic use.

5.2.3.3 Transportation schedule

The transportation service provider should establish a transportation schedule in accordance with the available transportation route(s) and requirements requested by the client in the timeframe required to maintain quality of cells. A transportation route should be capable of handling from the origin to the destination and through the transportation mode requested by the client. This can include multiple legs and modes of transportation.

The transportation service provider should investigate the feasibility of the schedule before determining the schedule.

The transportation service provider should examine the transportation schedule periodically.

The transportation schedule should be re-examined when changes occur in the availability of airlines and aircraft, which are critical for accepting dry shippers. The transportation schedule should also be re-examined, if relevant changes can impact the determined schedule. The transportation service provider should communicate with the client, in case the schedule is found not feasible.

NOTE Changes in the transportation schedule can occur for cell therapies. The frequency of change depends, in part, on the type of cell therapy.

5.2.3.4 Precautions/prohibitions

The transportation service provider should establish the list of precautions and prohibited operations to be considered during transportation.

The list of precautions and prohibited operations is identified considering external factors that can adversely affect the cells.

The following are examples of precaution/prohibitions during transportation:

a) minimum vibration;

b) shock/drop;

c) no overturning/tilting;

d) no opening of packages;

e) instructions for avoiding X-ray imaging (including cargo carrier X-ray) by a document and/or labelling.

NOTE Transportation service providers can have qualified processes and documentation to secure cargo (hold or hand carry) and enable cell shipments to be exempted from the X-ray process. This can be performed through various methods and is dependent on local requirements. For example, a shipper can have Known Consignor status, the transport provider can also hold this status and maintain a chain of custody (relevant documentation completed) to the airline and hand in without the X-ray being necessary (or utilize detection dogs, etc.). This is a controlled process and where it is permitted can satisfy X-ray avoidance requirements. This is not possible in all countries. Customs agencies have the right to inspect packages at any time and can do so after the hand in has been completed to the airline handlers and upon arrival to their territory. They can choose to inspect a shipment via an X-ray machine. Therefore, X-ray avoidance cannot be guaranteed.

5.2.3.5 Specific procedures for cell transportation

5.2.3.5.1 General

The transportation service provider should establish specific procedures for cell transportation based on the client requirements.

The specific procedures for cell transportation can include:

a) pickup procedure;

b) handling procedure;

c) delivery procedure.

5.2.3.5.2 Pickup procedure

Pickup of cells for therapeutic use by the transportation service provider can take place in person or in a way approved according to an agreement between the transportation service provider and the client.

Pickup procedure including implementation of risk assessment can include:

a) the rules for professional conduct, including appearance of personnel;

b) on-site dialogue with clinical staff at pickup of the package;

c) identification of personnel at pickup of the package;

d) identification of package to be picked up.

5.2.3.5.3 Handling procedure

Handling procedure includes the measure for ensuring handling condition provided from the clients and the cell transportation specification.

Handling procedure can include:

a) transportation mode and transportation route to use;

b) procedure for carrying out to take precautions/prohibitions;

c) procedure for monitoring temperature to assure insulation.

5.2.3.5.4 Delivery procedure

Delivery of cells for therapeutic use by the transportation service provider can take place in person or in a way approved according to an agreement between the transportation service provider and the client.

Delivery procedure can include:

a) the rules for professional conduct, including appearance of personnel;

b) on-site dialogue with clinical staff at delivery of the package;

c) identification of personnel when delivering the package;

d) identification of delivery package.

5.3 Risk management, verification and validation

5.3.1 Risk management

5.3.1.1 General

Risk during cell transportation is managed through risk assessment and risk control.

Plans for alternative means of transportation or shipping in case of emergency shall be established.

5.3.1.2 Risk assessment

The transportation service provider should identify potential hazards causing deviations and their probability of occurrence. The transportation service provider should evaluate the entire supply chain and its components such as shipping containers, transportation modes, external service providers, and classify these potential hazards based on a pre-set procedure.

The procedure should ensure that:

1) the extent of the deviations is determined;

2) the criteria for determining the probability of occurrence is defined;

3) the levels of risks are defined based on comprehensive assessment of deviations;

4) the probability of occurrence, and consequences of that occurrence, is evaluated as part of the risk mitigation.

The following are examples of potential hazards:

a) ordering mistake;

b) misplacement during transportation with no ability to actively trace;

c) delay in customs clearance processing;

d) temperature deviations;

e) failure of shipping container;

f) traffic delays;

g) natural disaster;

h) mix-up;

i) spills;

j) contamination;

k) breakage of primary containers.

5.3.1.3 Risk control

The transportation service provider should establish a cell transportation specification to mitigate risks based on the results of the risk assessment.

The following are examples of means to control risks:

a) alteration of transportation procedure;

b) establishment of emergency procedures;

c) additional monitoring of temperature, physical conditions, shipping container integrity, location service/GPS, etc.

The transportation service provider should review the cell transportation specification, when appropriate risk control procedures are designed. When new risk occurrences are determined, all risks should be assessed as it pertains to fulfilling the client's requirements.

NOTE 1 While it is impossible to eliminate the risk of human error or transportation delays, a holistic digital integration of processes is preferable. Best practice is to use processes, tools and data to monitor and manage the movement of biological materials.

NOTE 2 Best practice is to perform an approach that considers data capture from the start of sample collection through to treatment that tracks key variables including temperature essential to the quality and viability of cells for therapeutic use.

5.3.2 Verification and validation

The transportation service provider should verify the transportation route identified in the cell transportation specification.

The transportation service provider may make use of the following objective evidence for verification:

a) transport testing under the most adverse location and environment;

b) simulation testing;

c) data from past transports;

d) GPS monitoring and documentation of transportation travel route.

The client can request a validation of the client's requirements for a specific intended use or application. This is expected to be performed through cooperation between the transportation service provider and the client. When evidence of verification method has been documented, it can be useful for the validation.

6 Best practices for shipping container and labelling

6.1 General

A package comprises cells, shipping container and label. Best practices should be used to ensure safe transportation and maintain quality of the cells for therapeutic use. The specific requirements for shipping containers and labelling should be agreed upon in the contract between the transportation service provider and the client. This clause discusses best practice recommendations for shipping containers and labelling of cells for therapeutic use.

6.2 Shipping container

6.2.1 Shipping container systems

A shipping container for transportation should be designed to protect the integrity of the cells for therapeutic use and the health and safety of individuals in the immediate area. It is recommended that the shipping container consists of three layers, as follows.

Primary container: The primary container that directly contains the cells for therapeutic use.

Secondary container: The secondary container that encloses the primary container(s) in order to prevent external leakage of cells for therapeutic use in case of primary container breakage or leakage.

Outer container: The outer container inside which secondary containers are placed with suitable cushioning material in order to maintain the required condition and to protect their contents from outside influences, such as physical damage, during transportation.

NOTE 1 There are cases, for example such as domestic shipment, when a secondary container is not necessary.

NOTE 2 There are cases when a container includes a mechanism to release gas as needed (an example is liquid nitrogen dewar).

6.2.2 Shipping container requirements

The shipping container should be established and maintained to preserve the integrity and safety of cells during transportation. Shipping containers should be tamper-evident.

As primary container it is recommended to use watertight leak-proof container to contain the cells for therapeutic use. Primary containers should be sealed to prevent leakage. Primary containers shall not allow cross contamination.

If a secondary container is used it should enclose the primary container as a durable, watertight and leak-proof container. Several cushioned primary containers can be placed in one secondary container. If necessary, additional absorbent material may be placed into the secondary container in order to absorb all fluid in case of breakage or leakage. Any additional absorbent material should be pre-conditioned to be at the containers internal temperature to increase the containers ability to maintain temperature for the duration of the shipment.

NOTE 1 A secondary container dedicated for each batch can prevent cross contamination in case of leakage.

When needed, either a primary container or a secondary container should accommodate requirements concerning prevention of humidity, light exposure and air pressure.

The outer container should be made of material adequate to withstand leakage of contents, shocks, pressure change and other conditions incident to ordinary handling during transportation. The outer container should include handling instructions.

When needed, overpacks which cover an outer container may be used.

Recommendations for situations that require opening of the shipping container should be covered in the agreement between the transportation service provider and the client. For some classes of therapeutic samples, opening of containers can be absolutely prohibited.

Each reusable container should be controlled with all performance, commodity, cleaning and maintenance records maintained for the container and any reusable components or accessories.

When shipping containers capable of temperature control are used, accompanying documents, including information on the specification of products and the assurance that such functionality has been adequately validated, should be reviewed by the client or the transportation service provider, depending on their agreement.

NOTE 2 The following are examples of temperature control containers:

a) Insulating with cooling/heating materials including:

   1) dry ice; and

   2) phase change material;

b) active temperature-controlled systems;

c) dry shipper charged with liquid nitrogen.

NOTE 3 Specifications for environment maintaining instruments, can include:

a) performance ranges;

b) back-up systems;

c) maintenance documentation.

6.3 Labelling of the shipping container

6.3.1 Information to be labelled

6.3.1.1 General

The label of the shipping container should include necessary information for transportation.

The following are examples of necessary information for transportation:

a) location and name of sender and receiver;

b) emergency contact details for emergency management;

c) unique identifier (see 6.3.1.2), such as product code;

d) handling of the shipment (e.g. temperature requirement, orientation, fragile contents, dangerous goods).

Shipping container labels need special attention, because an identifier traceable to both biohazard information and patient-specific information can be required in specific areas of the packaging.

The transportation service provider should place the label, including information, on the shipping container.

6.3.1.2 Unique identifier

A unique identifier should be assigned to the shipping containers to allow traceability of any cells for therapeutic use to its donor and to all records describing the handling and final disposition of the product.

When a single product of cells for therapeutic use is stored in more than one container, there should be a system to identify each container.

When cells for therapeutic use, donor samples and product samples are correlated, there should be a system to identify each container.

When the transportation service provider handles unique identifiers and supplemental identifiers in their operations, the transportation service provider should retain this unique identifier, and should ensure that supplemental identifiers are not lost but are linked and tracked.

6.3.2 Physical requirements for the label

The label should be clear, legible, and completed using ink that is indelible to all relevant agents. The label should be capable to withstand attempts to be defaced, destroyed, removed, altered, obliterated or obscured by a deliberate act.

When applicable, print-on-demand label systems may be used, in condition that the labels on the templates approved by agreement between the transportation service provider and the client have been validated to confirm accuracy regarding identity, content and conformity.

When the label has been affixed to the container, sufficient area of the container should remain uncovered to permit inspection of the contents.

When cells for therapeutic use are re-packaged, outer containers should be relabelled and all remaining labels on outer container should be removed to avoid shipping errors.

6.3.3 Handling of labels

When outer containers or overpacks are to be reused, the label for the previous transportation place on each container or overpack should be destroyed.

Stocks of unused labels representing different products should be stored in a controlled manner to prevent errors.

7 Operation

7.1 General operation

7.1.1 General

Cell transportations are operated considering elimination of risks to the health and safety of employees and patients.

Cell transportations are carried out according to the following steps.

7.1.2 Preparation of shipment

The client should control preparation of shipment, including:

a) the labelling in a manner adequate to prevent mislabelling or misidentification of cells for therapeutic use, product samples and associated records;

b) the setting of data loggers, when needed;

c) the preparation of shipping container(s) in appropriate conditions.

NOTE These processes can be executed either by the client, the sender or the transportation service provider according to their agreement.

7.1.3 Transportation

The transportation service provider should conduct transportation in accordance with the cell transportation specification.

In order to preserve the identity of cells for therapeutic use throughout the process, and to assure safety of payload, a transportation provider should not open the container once sealed.

The transportation service provider should establish and maintain records for each process of cell transportation.

The following are examples for records of transportation:

a) time of pickup;

b) name and signature of personnel who handed package to transportation service provider;

c) name and signature of transportation service provider personnel who picked up package;

d) time of delivery;

e) name and signature of transportation personnel who handed package to receiver;

f) name and signature of receiver;

g) visual inspection conclusion.

NOTE There are cases when name and signature of personnel can be accompanied with his/her job title or responsibility.

7.1.4 Inspection at the time of delivery

The transportation service provider should ensure that the shipment is visually inspected at the time of delivery based on a pre-set procedure.

Examples of inspection include checking:

a) physical damage of outer container;

b) liquid leakage outside of the outer container;

c) damage of tamper proof seals of outer container.

NOTE Other than inspection at the time of delivery, reinvestigation of the shipment can be carried out after delivery. The following are examples of reinvestigation:

a) leaks from the primary container, that do not surface to the outer container;

b) disposition of primary container in the package;

c) temperature, and other data acquired from the data logger.

7.2 Traceability

The transportation service provider should ensure traceability.

The following are examples of method to ensure traceability:

a) tracking all pickup locations, times, and signatures;

b) monitoring with data logger(s) to measure temperature, humidity, pressure, shock, tilt, etc.;

c) IT systems and data management;

d) tamper evidence with physical and/or electronic seals;

e) GPS locator and/or active data logger for monitoring of cells for therapeutic use during transportation;

f) recording system when transferring package to external service providers;

g) appropriate recording system (e.g. control of all reusable shipping containers, their performance, accessories or data loggers).

