

Competency Assessment: Safe use of dry shippers and/or dry ice

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Purpose

This document can be used to help prompt consideration and recording of the competencies that are needed **to work safely with dry shippers and/or dry ice.**

This assessment covers competencies required for initial receipt of a low temperature shipment up until the point at which the shipping container is opened. A separate competency assessment is available relating to thawing cryopreserved cell-based therapeutic products.

This document contains two parts:

Part A: Template Checklist

Part B: Assessor Guidance Notes.

A process flow is provided on the next page to illustrate how parts A and B should be used. It is advisable to repeat the competency assessment after any change in local processes, staff duties or a prolonged period without conducting this type of work.

Process flow

Amend the template checklist

Training assessor and/or local manager(s) should adapt the **template checklist** (Part A) according to the local environment, procedures and roles/responsibilities of each member of staff. Amend the recommended reading list, signposting to local documents and training information. Remove any irrelevant information and edit competency requirements as appropriate.



Prepare for the assessment

Supply the learner with a copy of the amended competency checklist that should signpost them to the relevant local documents and training opportunities. Arrange a 1:1 meeting for the learner and training assessor to discuss the competency assessment checklist (either in person or remotely).



Carry out the assessment

It is recommended to carry out the assessment via interactive conversations, rather than relying on written communication. The assessor can use the **assessor guidance notes** to help determine whether learners have successfully demonstrated competencies around safe use of dry shippers and/or dry ice.



All competencies
satisfactorily
demonstrated?

NO



If gaps in knowledge are identified, signpost to where the learner can access more information and arrange a follow up assessment.

YES



Record the completed
competency assessment
according to
local practices.



Part A:

Template Checklist

This **template checklist** should be considered as a starting point rather than an off-the-shelf document that is ready for local implementation. The template checklist requires local adaptation by the training assessor and/or local manager(s) according to the local environment, procedures and the roles and responsibilities of each member of staff. The list of competency requirements should not be considered as exhaustive and assessors are encouraged to add, edit or delete information as appropriate. Users should remove information that is not relevant in the local setting. For example, if dry ice is not used locally, remove all references to dry ice and focus on competencies required for the use of dry shippers. Amend the recommended reading list as appropriate, adding in local documents and training information. The locally adapted checklist should be made available to the learner in advance of their competency assessment, to allow them to prepare and an opportunity to address any training gaps.

The adapted checklist can then be completed by the assessor together with the learner to provide a written record of the competency assessment. The checklist does not need to be completed in one sitting. If gaps are identified in the learner's knowledge, the checklist can be revisited after a period of (re-)training. Once the checklist has been completed and signed, a copy should be retained by the learner, and the assessor should ensure that training records are updated according to local practices.

Separate **assessor guidance notes** (part B) are also available; these should be used by the assessor to help determine whether the learner has successfully demonstrated the competencies required.

A draft recommended reading list is provided on the next page. Relevant local information should be added to this list. This may include standard operating procedures (SOPs), policies and risk assessments, plus details of applicable study days or training resources.

The form has been completed using an illustrative example of a staff member who has been assessed for competency to work with dry shippers but who will not work with dry ice.

Competency Assessment: Thawing cryopreserved cell-based therapeutic products



| Resource | Location | Link/details |
|--|--|---|
| Safe use of low temperature transport vessels e-learning module | Advanced Therapies e-learning programme hosted on e-Learning for Healthcare platform | https://portal.e-lfh.org.uk/Component/Details/648764 |
| Exemplar risk assessments | SPS website | https://www.sps.nhs.uk/articles/handling-dry-ice-and-vapour-phase-nitrogen-shippers-advice-for-hospital-pharmacies/ |
| The role of pharmacy in the successful delivery of ATMPs – Information for Chief Pharmacists | SPS website | https://www.sps.nhs.uk/articles/atmps-the-role-of-pharmacy-in-the-successful-delivery-of-advanced-therapy-medicinal-products-atmps-information-for-chief-pharmacists/ |
| Dry ice training course | NIHR CRN West of England Research Hub | https://www.wetraining.nihr.ac.uk/nihr-learn |
| E.g. Safe use of dry ice SOP | Q-Pulse | Document XXX v1.0 |
| E.g. Administration of Immune Effector Cells | Q-Pulse | Document XXX v1.1, Point 3.6-3.8 |
| E.g. Internal pedestrian transport of liquid nitrogen | Intranet | Document XXX, Appendix 3 |
| E.g. Manual handling procedure | Intranet | Document XXX, Point 5.2 |
| E.g. Local risk assessment X | Datix | Document XXX v1.2 |
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| | | |
| | | |



Competency assessment

| Requirement | Assessment method(s) | Competency evidenced (assessor initials/date) |
|--|----------------------|--|
| Completion of safe use of low temperature transport vessels e-learning & assessment. | Certificate | |
| Can describe what a dry shipper is, how it works & how it is used. | Verbal | |
| Can describe what dry ice is, how it works and how it is used. | Verbal | |
| Has read and understood relevant risk assessments relating to use of dry shippers/dry ice. | Verbal | |
| Can identify who has overall responsibility for the governance and management of the product(s) being transported. | Verbal | |
| Can describe procedures for secure movement of ATMP shipments into and through the hospital site. | Verbal | |
| Can describe specific location(s) for named therapeutic products to be taken to or stored in. | Verbal | |
| Can discuss the importance of maintaining the product at an appropriate temperature until it is administered. | Verbal | |
| Demonstrates thorough inspection of shipment on receipt. | Observation | |
| Can describe risk of cold burn injury, how to reduce risk and first aid procedures in event of injury. | Verbal | |
| Can discuss risk of asphyxiation, how to reduce risk and first aid procedures in event of injury. | Verbal | |
| Completion of local manual handling training within last 3 years. | Certificate | |
| Can describe how to safely move dry shippers. | Verbal | |
| Can describe the process for returning dry shippers to sending laboratories. | Verbal | |
| Can describe how dry ice should be disposed of safely and where this can be done locally. | Verbal | |

Competency Assessment: Thawing cryopreserved cell-based therapeutic products



Outcome:

| | |
|--|--|
| <p>Have the required competencies been demonstrated for the safe use of dry shippers and/or dry ice? If certain competencies are not applicable, please explain why.</p> | <p>e.g: Yes. Dry ice is not used in this department, so competencies 3 & 15 do not apply. Example Trainee is competent to safely work with securely closed dry shippers.</p> |
| <p>Please detail any further training/ re-assessments required & by what date.</p> | |
| <p>Any additional comments.</p> | <p>e.g: Competency #9 was observed by Ann Example, Cell Therapy Facility Manager: <i>Ann Example 0107/2021</i></p> |

Authorisation:

| Trainee | Assessor |
|-----------|-----------|
| Name | Name |
| Signature | Signature |
| Date | Date |

Please file a copy in trainee's individual training record and update local training database or learner management system as appropriate.



Part B:

Assessor Guidance Notes

Note: Individuals being assessed (learners) should not use this Part B. These guidance notes are intended for use by training assessors.

This document provides **assessor guidance notes** to help determine whether learners have successfully demonstrated competencies around the **safe use of dry shippers and/or dry ice**. This assessment covers competencies required for initial receipt of a low temperature shipment up until the point at which the shipping container is opened. A separate competency assessment is available for thawing cryopreserved cell-based therapeutic products.

These guidance notes provide further detail on the knowledge and skills that the learner needs to demonstrate in order to meet the competency requirements. Suggested questions are provided for the assessor to pose, but these should not be considered either mandatory or exhaustive – ideally interactive conversation(s) between the learner and assessor can be used to explore the learner's understanding, discuss best practice and answer any questions. The level of detail in the learner's answers should be appropriate to their role and responsibilities. Some adaptation of the expected answers may be required according to local procedures.

**Competency Assessment:
Thawing cryopreserved cell-based
therapeutic products**

| Requirement | Notes to assessor and expected answers | Assessment method(s) |
|---|--|----------------------|
| <p>Completion of safe use of low temperature transport vessels e-learning & assessment.</p> <p><i>Ask to see a certificate evidencing successful completion of this e-learning module.</i></p> | <p>This e-learning module is available to all NHS staff via e-Learning for Healthcare – ask the learner to access and complete the module. If they have already done so, you may wish to ask to see a copy of their certificate.</p> | <p>Certificate</p> |
| <p>Can describe what a dry shipper is, how it works and how it is used.</p> <p><i>Can you tell me how a dry shipper is prepared for use?</i></p> <p><i>Is there liquid nitrogen at the bottom of the shipper?</i></p> <p><i>How cold is it inside a shipper?</i></p> | <p>A specially designed shipping container used to transport 'cryopreserved' (frozen while preserving cell viability) biological material at cryogenic temperatures (usually below -150°C). Prior to use a dry shipper is charged by filling it with liquid nitrogen, which is trapped by an absorbent material surrounding an inner chamber. Before the dry shipper is loaded, excess liquid nitrogen is poured away by careful tipping. During the shipment, the inner chamber is continuously filled with escaping nitrogen vapour, maintaining the low temperature for a validated time period (some containers stay cold for just a few hours, while others can maintain cryogenic temperatures for days when kept in an upright position). When prepared correctly, a dry shipper does not contain free liquid nitrogen (although a residual amount may remain at the bottom of the chamber).</p> | <p>Verbal</p> |
| <p>Can describe what dry ice is, how it works and how it is used.</p> <p><i>What is dry ice? How cold is it?</i></p> | <p>Dry ice is solid carbon dioxide (CO_2) in the form of blocks, slices or pellets. At normal temperatures dry ice sublimates (changes from a solid state directly into a gas) without passing through a liquid phase. Dry ice is very cold (approx. -78.5°C) and can be used to maintain a low temperature inside a suitably insulated shipping container.</p> | <p>Verbal</p> |

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

| Requirement | Notes to assessor and expected answers | Assessment method(s) |
|---|--|----------------------|
| <p>Has read and understood relevant risk assessments relating to use of dry shippers/dry ice.</p> <p><i>Which risk assessments have you read that are relevant to using dry shippers/dry ice?</i></p> <p><i>Do you have any questions about those risk assessments?</i></p> | <p>Local risk assessments must be in place for all work involving dry shippers or dry ice. Exemplar risk assessments are available (see recommended reading on page 2 of competency assessment) which can be used as a basis for conducting local assessments. These should then be signposted under recommended reading. Ask the learner to confirm which risk assessments they have consulted and if they have any questions.</p> | <p>Verbal</p> |
| <p>Can identify who has overall responsibility for the governance and management of the product(s) being transported.</p> <p><i>Who has overall responsibility in this hospital for overseeing governance relating to CAR T cell products? (or whichever product type is relevant for the learner)</i></p> | <p>This will depend on the type of product being transported. For advanced therapy medicinal products (ATMPs), since these are medicinal products, they are subject to the same requirements as for other medicines. The Chief Pharmacist has overall responsibility for governance and management of ATMPs. Pharmacy must ensure that ATMPs are of appropriate quality for their intended use. Most current usage is in clinical trials (advanced therapy investigational medicinal products, or ATIMPs), but ATMPs are beginning to become available as licensed and unlicensed medicines. Requests to use ATMPs should be scrutinised by an appropriate multidisciplinary committee e.g. Medicines Management or New Interventional Procedures Committee, or a Genetic Modification Safety Committee if gene therapy or Gene Therapy Advisory Committee for ATIMPs.</p> | <p>Verbal</p> |

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

| Requirement | Notes to assessor and expected answers | Assessment method(s) |
|---|---|----------------------|
| <p>Can describe the people and procedures involved in securely moving and storing dry shipper/dry ice shipments into and through the hospital site.</p> <p><i>What is a key consideration when moving or storing shippers that contain a therapeutic product?</i></p> | <p>The learner should emphasise that therapeutic products must always be kept safely and securely, either in the custody of suitably trained healthcare professionals or transport staff, or in a locked medicines storage area. They should be able to name the key personnel/teams locally. If products are transported and stored on site, this must be done in accordance with any specific requirements of the transport vessel e.g. its validated hold time at the appropriate temperature.</p> | Verbal |
| <p>Can describe specific location(s) for named therapeutic products to be taken to or stored in.</p> <p><i>For the XXX trial, where are the shippers going to be taken?</i></p> | <p>For assessor to complete according to local arrangements (e.g. designated secure shipper storage room or designated secure, temperature-monitored fridge or freezer). If not applicable, indicate N/A on the assessment checklist.] For clinical trials this can be bespoke as per the trial requirements.</p> | Verbal |
| <p>Can discuss the importance of maintaining the product at an appropriate temperature until it is administered.</p> <p><i>Why is it important to keep the product at the right temperature?</i></p> <p><i>What would you do if the shipper temperature went out of range?</i></p> | <p>Possible implications if shipment conditions fall out of specification (i.e. damage to the living cells which may render the therapy ineffective). Describe the appropriate course of action to follow if this happens – likely to require urgent discussion involving the therapy manufacturer, responsible pharmacist and the patient’s consultant, but refer to local policy and product/trial-specific protocol.</p> | Verbal |

Competency Assessment: Thawing cryopreserved cell-based therapeutic products

| Requirement | Notes to assessor and expected answers | Assessment method(s) |
|---|---|---|
| <p>Demonstrates thorough inspection of shipment on receipt.</p> <p><i>Can you take me through how you would inspect a closed shipper/dry ice container?</i></p> | <p>Inspection should include check for signs of damage to the shipping container (if concerned, contact the sending laboratory immediately), confirmation of intact security seal(s) if present (number matched to documentation if applicable), within-range reading from any temperature logger and any other monitoring (e.g. tilt meter), with contemporaneous completion of relevant documentation.</p> | <p>Observation (or verbal if deemed sufficient)</p> |
| <p>Can describe risk of cold burn injury, how to reduce risk and first aid procedures to follow in event of injury.</p> <p><i>Can you describe the risk of a cold burn injury from using a dry shipper/dry ice?</i></p> <p><i>How can you reduce the risk?</i></p> <p><i>What steps should you follow in case of cold burn injury?</i></p> | <p>Contact with liquid nitrogen, dry ice, cold vapours or super-cooled surfaces (e.g. metal chamber inside shipper, or cassettes used to protect bags during transit) may result in cold burn injury. Cryogenic burns are initially completely painless as the skin is frozen. As the burn begins to thaw an individual will experience intense pain and may go into shock.</p> <p>PPE should be appropriate to the task and readily available. All users of low temperature transport vessels should have access to non-absorbent, insulated thermal gloves. These should be worn when handling anything that has been in recent contact with dry ice or cold vapour. Insulated gloves are not designed for the hands to be put into liquid nitrogen. Unprotected skin can freeze to super-cooled surfaces and flesh may be torn on removal. Before reaching into a dry shipper, metal wrist/hand jewellery should be removed.</p> <p>Exposure to cold vapours may affect the delicate tissues of the eyes, therefore safety goggles should be available for staff to wear when removing items from a dry shipper or from a dry ice shipment. Stand clear of the cold vapours that are released when a low temperature transport vessel is opened.</p> <p>First aid procedures for a cold burn: loosen restrictive clothing (but do not remove any clothing frozen to the tissue) and flush the area with tepid water. Do not apply heat or rub the affected area. Cover with a loose, sterile dressing and keep the casualty warm and at rest. Obtain medical assistance immediately.</p> | <p>Verbal</p> |

**Competency Assessment:
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therapeutic products**

| Requirement | Notes to assessor and expected answers | Assessment method(s) |
|---|---|----------------------|
| <p>Can discuss risk of asphyxiation, how to reduce risk and first aid procedures to follow in event of injury.</p> <p><i>Is asphyxiation a big risk when working with dry shippers/dry ice?</i></p> <p><i>What can you do to reduce the risk of asphyxiation when working with a dry shipper or dry ice?</i></p> <p><i>What should be done if asphyxiation occurs?</i></p> | <p>Risk of asphyxiation is very low with correct use of a dry shipper or small quantities of dry ice in a well-ventilated area. A formal risk assessment should be undertaken for all areas where low temperature transport vessels are used or stored. Dry shippers and dry ice should never be stored in confined spaces without good ventilation. There should be appropriate signage and access restrictions in place. Where it is necessary to move a dry shipper in a lift, steps must be taken to ensure this is done safely, including completion of a detailed risk assessment and establishing emergency procedures. Where asphyxiation has occurred, the affected person should be moved to a well-ventilated area. Rescuers should not put themselves at risk; the area should not be entered unless considered safe. The casualty should be kept warm and rested whilst medical attention is obtained. If breathing has stopped, resuscitation should be commenced by a trained first aider.</p> | <p>Verbal</p> |
| <p>Local manual handling training completed within last 3 years.</p> | <p>Operators should follow relevant manual handling risk assessments relating to the activities they are required to perform.</p> | <p>Certificate</p> |
| <p>Can describe how to safely move dry shippers.</p> <p><i>Can you talk me through how dry shippers should be safely moved?</i></p> <p><i>Why do you need to keep dry shippers upright?</i></p> | <p>Shippers must always be kept upright (otherwise their ability to maintain low temperature may be compromised). Shippers should be moved using a platform trolley or wheelbase, using a pushing action rather than pulling, and moving across a solid and smooth surface. Shippers must be handled with care. Damage to a shipper may result in vacuum failure, rapid nitrogen venting and loss of temperature control, which could compromise the integrity of the therapeutic product. Local procedures must be followed for safely transporting dry shippers in lifts where this is necessary (learner should be able to describe risks associated with moving a dry shipper within the enclosed space of a lift – see #11).</p> | <p>Verbal</p> |

**Competency Assessment:
Thawing cryopreserved cell-based
therapeutic products**

| Requirement | Notes to assessor and expected answers | Assessment method(s) |
|---|--|----------------------|
| <p>Describe the process for returning dry shippers.</p> <p><i>What happens to an empty dry shipper once a product has been administered?</i></p> | <p>As appropriate to role – e.g. return to pharmacy/stem cell lab or other designated secure location; versus liaise with the sending laboratory to arrange shipper return. Some couriers may require empty dry shippers to be labelled as being “EMPTY”. The learner should demonstrate an understanding of the need to return the empty shipper to the sending laboratory so that it can be recharged and made available for subsequent shipments.</p> | <p>Verbal</p> |
| <p>Can describe how dry ice should be disposed of safely and where this can be done locally.</p> <p><i>Where would you dispose of dry ice locally?</i></p> <p><i>What must you never do when disposing of dry ice?</i></p> | <p>Keep dry ice in an appropriately insulated, non-air-tight container, and place in a secure, well-ventilated area (ideally in a fume hood or secure outdoor area) to allow it to sublime (disperse). Never tip into drains or down the sink (could embrittle drains, and contact with water increases sublimation and therefore asphyxiation risk). Do not store in a conventional fridge or freezer as it may damage the device due to the extreme low temperatures. Carbon dioxide is heavier than air, so is likely to accumulate at lower levels. Dry ice should not be left to sublime near to a ramp or stairwell where the CO₂ gas may become concentrated at a lower level.</p> | <p>Verbal</p> |