Handling Dry Ice and Vapour Phase Nitrogen Shippers – advice for hospital pharmacies

Pan UK Pharmacy Working Group for ATMPs

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The first stop for professional medicines advice

Introduction

The Pan UK Pharmacy Working Group (PWG) for Advanced Therapy Medicinal Products (ATMPs) acts as an expert and informed body to support the activities of UK Pharmacies to facilitate ATMP usage. The group consists of pharmacists and stem cell laboratory colleagues from across the UK that specialise in the governance, prescribing, administration and monitoring of ATMPs. The aims of the group are to promote good practice, and to identify and resolve pharmacy issues to maximise the effectiveness and development of services for hospitals to administer advanced therapies.

Handling Dry Ice and Vapour Phase Nitrogen Shippers

Many ATMPs achieve greatest stability at ultra-low temperatures. The use of -80°C and below is commonplace to achieve optimal product shelf life. It is therefore likely that, as the usage of ATMPs grows, pharmacy departments will be required to receive shipments and store products at ultralow temperatures. The advice contained in this document and the associated training module is not limited to ATMPs – it is suitable for all medicines requiring receipt and storage at ultra-low temperature.

The content of this document is in 3 parts:

1) Pharmacy Risk Assessments for the receipt of products at ultra-low temperatures.
2) Links to electronic training resources on the Safe Use of Low Temperature Transport Vessels
3) A template competency training checklist for use in Pharmacies, supported by assessor guidance notes.

Risk Assessments

It is recommended that before departments first receive shipments in Dry Ice or in Vapour Phase Nitrogen Shippers a risk assessment is documented, to ensure that staff are aware of the risks and that procedures are in place to mitigate the risks as far as possible. Two examples of risk assessments for departments unfamiliar with these shipments have been provided below. These can be used as a basis for any local assessments required.

The Risk Assessment exemplars direct users to an e-learning module and competency assessment documents to assist in staff training. These resources are discussed further on pages 15 – 24.

Pharmacy Risk Assessment Example – Medicine Shipments received on Dry Ice

Notes for completion

A – Complete for your department, altering fields as necessary.

B – Some Advanced Therapy Medicinal Products (ATMPs) may be potentially infectious e.g. *in vivo* gene therapy using viral vectors. Product-specific risk assessments should be conducted to ascertain risks posed by the ATMP and to determine appropriate risk reduction measures.

C – Dry Ice presents an asphyxiation hazard in confined spaces. Always seek professional advice about ventilation of storage areas. Advice regarding air changes/ventilation can be obtained from your Estates department. Of relevance is size of the room where the package is opened, whether there are any external windows or doors, and working air vents. The Health and Safety department can then assess if ventilation is adequate depending on the quantity of Dry Ice likely to be present at any one time. Health and Safety will also undertake a COSHH assessment. If your local H&S team are not confident assessing ventilation requirements, consider contacting a specialist for advice.

See BOC:
https://www.boconline.co.uk/en/health-and-safety/workplace-safety/assessing-risks/

Or Contronics:
https://www.contronics.co.uk/

Consider the use of room and personal CO_2 monitors (depending on frequency of deliveries and the process at your site). All areas where Dry Ice is stored or used must be properly identified, with warning signs and emergency contact details in and around storage areas.

D – Styrofoam is an appropriate storage material for Dry Ice since it is insulated and not airtight.

E – Ensure that staff are aware of the labelling requirements for Dry Ice (see notepad section below) and that shipments containing Dry Ice are labelled correctly; if they are not or do not include a material safety datasheet for the Dry Ice, speak to the supplier.

F – Speak to your Health and Safety department if you are not able to allow sublimation (disposal) of the Dry Ice in a fume hood or a secure outside area. Dry Ice should not be left to sublimate near to a ramp or stairwell where the carbon dioxide gas (which is heavier than air) may become concentrated at a lower level. Never tip into drains or down the sink (could embrittle drains and contact with water increases sublimation and therefore asphyxiation risk).

G – Ensure SOP is detailed and explains what to do with the medication, packaging and Dry Ice as well as procedure for spillage (both for the contents of the package and the Dry Ice).

RISK ASSESSMENT FORM

Hospital:	X	**Location of Risk:**	Pharmacy stores
Directorate:	Pharmacy and Medicines Management	**Date Form Completed:**	16/9/2020

Risk Title
Dry Ice medicine shipment risks

Description of Risk:

Explain risk

Some medicines are received into the hospital pharmacy on Dry Ice (solid carbon dioxide) to maintain a low temperature (approx -80°C). This happens approximately every 2 weeks and packages contain a small amount (<5kg) of Dry Ice pellets. A number of staff members are usually in the pharmacy goods in area and staff will be rarely if ever working alone. There is a risk that staff can be harmed in a number of ways if they handle the Dry Ice incorrectly. There may also be risk of infection to staff or environment if contents are infectious or genetically modified. There is a risk to the therapeutic product if it is handled incorrectly or if the validated storage time is exceeded or acceptable temperature limit is breached.

Cause / Source / Event

At normal temperatures Dry Ice sublimes (changes from a solid state directly into a gas), releasing carbon dioxide gas, which is heavier than air and an asphyxiant. Large volumes of carbon dioxide gas can be released from a small volume of Dry Ice. The Dry Ice itself and its vapour are very cold, presenting potential for injury. The shipping container may present a manual handling risk. The shipment contents may be potentially infectious (see note B). ATMPs are very sensitive to changes in temperature and may be brittle when frozen; they must be handled very carefully and at constantly monitored temperatures.

Impact / Consequence

Asphyxiation (in high concentrations sublimed vapour may cause loss of mobility, consciousness and asphyxiation; low concentrations may cause increased respiration and headache), explosion (if placed in an airtight container), physical injury, cold burns, infection, damage to medicine, therapeutic failure.

Score Risk <u>without</u> Current Controls (Initial Risk Score)

Consequence	**4**	**X**	**Likelihood**	**5**	**=**	**Risk Rating**	**20**

Controls in Place:
1. Staff training – current informal ‘on the job’ training
2. Temperature resistant gloves worn when removing products from the shipment (suitable shoes as per uniform policy)
3. Do not store or open shipments in confined spaces with poor ventilation – pharmacy store goods in area suitable (see note C), never place Dry Ice in air tight containers, walk in fridges, small fridges or freezers or near to a ramp or stairwell (see notes D and F)
4. Keep shipment upright at all times
5. Staff must follow directions on the shipment regarding unpacking, placing in appropriate freezer ASAP, and temperature monitoring
6. Staff must follow directions on shipment and SOP X for disposal of Dry Ice and packaging and safe storage of the medication (see notes E&F&G)

Score Risk <u>with</u> Current Controls (Current Risk Score)						
Consequence	**4**	**X**	**Likelihood**	**3**	**=**	**Initial Risk Rating**	**12**

	Likelihood				
Consequence	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

	1-3	Low risk
	4-6	Moderate risk
	8-12	High risk
	15-25	Extreme risk

Gaps in Controls:
1. Gaps in training
2. Staff may be unaware that Dry Ice is inside a shipment – ensure they are aware of dangerous goods labels
3. Goggles and coveralls not usually worn when unpacking

Assurances:
1.
2.
3.

Gaps in Assurance:
1.
2.
3.

Actions Required to reduce risk rating:	Action Lead	Target Completion Date
1. All staff transporting or unpacking shipments on Dry Ice must undertake formal training and be designated as competent to handle Dry Ice. (see pages 15 - 24)		
2. First aiders in the department should be trained in cold burns and asphyxiation		
3. Ensure people only open Dry Ice shipments in designated area (e.g. not in clinical trials room).		
4. Goggles as well as gloves must be worn when unpacking. Arms and legs should be covered, consider use of lab coat or similar coverall.		

Notepad:

Put any supporting relevant information here that does not sensibly fit in the other sections but you feel is useful.

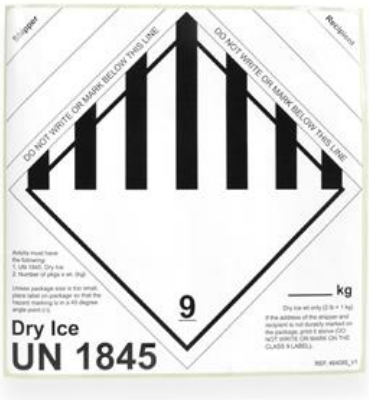
Consider the final destination of the medication and consider implication of moving a shipment around the hospital if this is required. If it does need to be moved it should be done by trained operators only. Use of lifts should be avoided wherever possible, however this is unlikely to pose a significant risk providing only a small amount (<5kg) of Dry Ice is carried in a suitable container. If in any doubt, professional advice should be sought to help assess the risk locally. Consider purchasing a personal CO_2 monitor.

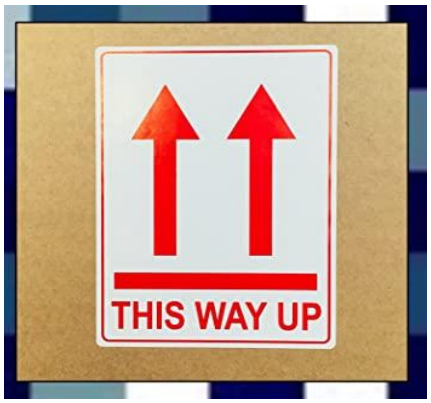
Trolley should not be necessary unless a manual handling risk is identified, but keep container upright (see this way up label below)

Dry Ice is classified as 'Dangerous Goods' under the transport regulations and therefore must be packed and labelled in accordance with these regulations before it will be accepted for transport by a courier.

The outside of the box **must** carry a HAZMAT Class 9 Miscellaneous label together with a carbon dioxide label:

UN 1845,
DRY ICE or CARBON DIOXIDE, SOLID
CLASS 9
PACKING GROUP 904





NET QUANTITY of DRY ICEDRY ICE PER PACKAGE .... kg

For safety data sheet see:
https://www.boconline.co.uk/en/images/tg-9390-carbon-dioxide-solid-v1.3._tcm410-39610.pdf

For more information see:
https://www.boconline.co.uk/en/images/dry-ice-bcga-guidelines_tcm410-39540.pdf

Considering all the information you have on the controls and assurances how would you rate the risk when the actions are completed (Target Risk Score):						
Consequence	**4**	**X**	**Likelihood**	**1**	**=**	**Target Risk Rating**	**4**

Main Risk Type: ***please tick one only***				
~~Clinical Care/Quality~~	~~Communication/PR~~	~~Compliance with Standards~~	~~Corporate Governance~~	~~Estates~~
~~Financial~~	**Health & Safety**	~~Information Governance~~	~~Infection Control~~	~~Legal~~
~~Safeguarding~~	~~Security~~	~~Social Care~~	~~Strategic~~	

Signature of Assessor	
Date of Assessment	
Risk Owner	
Signature of Clinical Board Director	
Date	

Pharmacy Risk Assessment Example – Medicine Shipments received in Vapour Phase Nitrogen Shipper

Notes for completion

A – Complete for your department altering fields as necessary

B – Some Advanced Therapy Medicinal Products (ATMPs) may be potentially infectious e.g. *in vivo* gene therapy using viral vectors. Product-specific risk assessments should be conducted to ascertain risks posed by the ATMP and to determine appropriate risk reduction measures.

C – Always seek professional advice about ventilation. Advice regarding air changes/ventilation can be obtained from your Estates department. Of relevance is size of the room where the shipper is stored and opened, whether there are any external windows or doors, and working air vents. The Health and Safety department can then assess if ventilation is adequate depending on the quantity of Nitrogen likely to be present at any one time. Health and Safety will also undertake a COSHH assessment. If your local H&S team are not confident assessing ventilation requirements, consider contacting a specialist for advice.

See BOC or Contronics
https://www.boconline.co.uk/en/health-and-safety/workplace-safety/assessing-risks/
https://www.contronics.co.uk/

Consider investment in an oxygen depletion monitor for the room or personal alarms for staff (depending on frequency of deliveries and the process at your site). All areas where dry Shippers are stored or used must be properly identified, with warning signs and emergency contact details in and around storage areas.

D – Consider installing an anchor point to secure shipper. A shipper containing a medicinal or therapeutic product must remain in the custody of a trained healthcare professional, or be stored securely in a locked medicines storage area. It cannot be stored in a locked cupboard inside a treatment room as dry Shippers should never be stored in confined spaces without good ventilation. Consider addition of a tamper evident security tag as the original tag will have been removed when checking the contents (include all steps in SOP and receipt checklist documentation).

E – Keep shipper upright at all times as the validated storage time depends on this (storing a dry shipper on its side or inverted can significantly compromise maintenance of ultra-low temperatures). A low base trolley or wheelbase should be used to move shipper on a level surface due to weight and need for shipper to remain upright.

F – Ensure SOP is detailed and explains what to do with the medication and shipper as well as procedure for spillage (both for the contents of the shipper and in unlikely event of liquid nitrogen spill) and return of the shipper if applicable. If the shipper is stored in the pharmacy/clinical area ensure that the SOP covers checking the temperature at specified intervals and procedure if shipper is increasing in temperature or near to the maximum storage time. The shipper may need to be returned to the supplier or contents relocated (with company/sponsor approval).

G – There should be minimal liquid nitrogen in a dry shipper but if some remains, gloves must not be exposed directly to liquid nitrogen as it can be rapidly absorbed. The receptacle holding the product must be lifted partly out of the shipper and held over the shipper to allow any liquid trapped in the can to drain back into the shipper before the product is removed. The liquid nitrogen level can be checked using a simple measuring stick and stainless steel cryo-tongs may be useful for the retrieval from the shipper.

RISK ASSESSMENT FORM

Hospital:	X	**Location of Risk:**	Pharmacy stores
Directorate:	Pharmacy and Medicines Management	**Date Form Completed:**	9/9/2020

Risk Title
Vapour Phase Nitrogen Shipper Risks

Description of Risk:

Explain risk

Some Advanced therapy medicinal products (ATMPs) may be received into the hospital pharmacy 'goods in' area and moved around the hospital in a Vapour Phase Nitrogen Shipper to maintain a low temperature of below -150°C. Pharmacy have not had experience of these Shippers before, however we are expecting a delivery in a shipper approximately once a month. A number of staff members are usually in the pharmacy goods in area and staff will be rarely if ever working alone.

There is a risk that staff can be seriously harmed in several ways (see below) if they handle the Vapour Phase Nitrogen Shipper incorrectly. There may also be risk of infection to staff or environment if contents are infectious or genetically modified. There is a risk to the therapeutic product if it is handled incorrectly or if the validated storage time is exceeded or acceptable temperature limit is breached.

Cause / Source / Event

Due to the nitrogen gas released, the manual handling risk, extreme cold (causing burns, or causing materials to be brittle and shatter) and potentially infectious contents (see note B) ATMPs are very sensitive to changes in temperature and brittle when frozen, they must be handled very carefully and at constantly monitored temperatures

Impact / Consequence

Asphyxiation (in high concentrations nitrogen vapour may cause loss of mobility, loss of consciousness and asphyxiation, low concentrations may cause increased respiration and headache), physical injury, cold burns, infection, damage to medicine, therapeutic failure.

Score Risk <u>without</u> Current Controls (Initial Risk Score)

Consequence	**4**	**X**	**Likelihood**	**5**	**=**	**Risk Rating**	**20**

Controls in Place:
1. Staff training – Shippers look different to other deliveries and staff know not to undertake tasks that they are not trained for and will ask for help if encounter shipper.
2.
3.

Score Risk <u>with</u> Current Controls (Current Risk Score)						
Consequence	**4**	**X**	**Likelihood**	**3**	**=**	**Initial Risk Rating**	**12**

	Likelihood				
Consequence	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

	1-3	Low risk
	4-6	Moderate risk
	8-12	High risk
	15-25	Extreme risk

Gaps in Controls:
1. Training in handling shippers and contents.
2. There are some deficiencies in personal protective equipment available in the department.
3. SOPs not yet available for process.

Assurances:
1.
2.
3.

Gaps in Assurance:
1.
2.
3.

Actions Required to reduce risk rating:	Action Lead	Target Completion Date
1. All staff transporting (see note E) or unpacking Shippers must undertake formal training and be designated competent to handle Dry Shippers see Pages 15-24.		
2. First aiders in the department should be trained in cold burns and asphyxiation		
3. Ensure people store and open Shippers in designated areas, with sufficient ventilation as assessed by H&S. Safe custody of medicines policy must always be adhered to and access to the medication must be restricted to trained staff only. SOPs must be written to cover receipt, storage, transport, and opening of the Shippers (see note F).		
4. Purchase temperature resistant gloves, goggles and lab coat or coverall to be worn when removing products from the shipper (suitable shoes as per uniform policy; arms and legs should be covered) (see note G). Also, liquid Nitrogen level measuring stick and stainless steel cryo-tongs.		
5. Establish procedure for return to the sending laboratory of empty dry shipper, or if necessary of dry shipper containing therapeutic product.		

Notepad:
Put any supporting relevant information here that does not sensibly fit in the other sections but you feel is useful. Consider the final destination of the medication and consider implication of moving a shipper around the hospital if this is required. If it does need to be moved it should be done by trained operators only. Use of lifts should be avoided wherever possible. 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. Key controlled lifts are strongly recommended to allow Shippers to be moved securely without accompanying the shipper. Where the use of lifts cannot be avoided, the following recommendations should be considered: • Operator to receive suitable training • Operator to carry an oxygen depletion monitor • Operator to have control of the lift to enable evacuation at next available floor • Lift to be fitted with emergency alarm/telephone • If lift is equipped with extraction fan this should be switched on • Do not transport in a lift a shipper that is venting gas • Do not vent the shipper whilst in a lift • Do not transport a leaking or defective shipper in a lift • Do not transport in a lift a shipper that has ice forming on the outside The transportation of dry Shippers in lifts containing product should be supervised/monitored outside the lift by a Competent Person who is aware of the potential hazards and of the action to take in an emergency. If in any doubt, professional advice should be sought to help assess the risk locally. For safety data sheet see: https://www.boconline.co.uk/en/images/10021831_tcm410-39604.pdf

Considering all of the information you have on the controls and assurances how would you rate the risk when the actions are completed (Target Risk Score):						
Consequence	**4**	**X**	**Likelihood**	**1**	**=**	**Target Risk Rating**	**4**

Main Risk Type: ***please tick one only***				
~~Clinical Care/Quality~~	~~Communication/PR~~	~~Compliance with Standards~~	~~Corporate Governance~~	~~Estates~~
~~Financial~~	**Health & Safety**	~~Information Governance~~	~~Infection Control~~	~~Legal~~
~~Safeguarding~~	~~Security~~	~~Social Care~~	~~Strategic~~	

Signature of Assessor	
Date of Assessment	
Risk Owner	
Signature of Clinical Board Director	
Date	

Recommended Training Resources

The Pharmacy Working Group for ATMPs recommend the use of a new e-Learning module 'Safe use of low temperature transport vessels' which has been produced to support people working with Vapour Phase Nitrogen Shippers and Dry Ice.

The module production was undertaken by NHSBT as part of work for the Midlands-Wales ATTC recognising that this was a gap for staff receiving and handling some ATMPs. It is suitable for all medicines which are shipped in these ways. It introduces Vapour Phase Nitrogen Shippers and Dry Ice shipments, explains the hazards of using these low temperature transport vessels and describes how they can be used and stored safely. There is a short e-assessment at the end of the course that generates a certificate for training records.

The module is the first part of an 'e-learning programme on 'Advanced Therapies' that will be available to all NHS and UK university staff via the e-Learning for Healthcare Hub: https://portal.e-lfh.org.uk/Component/Details/648764. Further e-Learning modules will be added to this programme as they become available.

For new users who need to register for access to the e-LfH hub, instructions are available on the e-LfH support page.

Designation of Competency

Having undertaken training, the competency of operators requires formal assessment and documentation. The Pharmacy Working Group for ATMPs recommends the use of the following competency assessment checklist to assist in this process. One checklist should be completed per team member. Assessor guidance notes are included on pages 20-24 to help assessors to determine whether competency requirements have been successfully demonstrated.

Competency Assessment:
Safe use of Vapor Phase Nitrogen Shippers and Dry Ice
Template Checklist

This document should be used to prompt consideration and recording of the competencies that are needed for staff to work safely with dry Shippers and Dry Ice.

The template should be adapted according to individual requirements, depending on 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.

Separate assessor guidance notes 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 page 2. 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.

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.

The checklist has been completed using an illustrative example of a staff member who will handle securely closed dry Shippers, but will not open them or handle the contents, or work with Dry Ice.

Recommended reading

Please add to and update this list to signpost towards relevant documents and training resources.

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	Included in this document	Pages 3-14
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/
SOP: example X	*Q-Pulse*	*Controlled document XXX-XXX- v1.1*
Risk assessment: example X	*Datix*	*Controlled document XXX-XXX- v1.2*

Competency assessment

No.	Requirement	Assessment method(s)	Competency evidenced (assessor initials)
1	Completion of safe use of low temperature transport vessels e-learning & assessment.	Certificate	*EA*
2	Can describe what a dry shipper is, how it works & how it is used.	Verbal	*EA*
3	Can describe what Dry Ice is, how it works and how it is used.	Verbal	*N/A*
4	Has read and understood relevant risk assessments.	Verbal	*EA*
5	Can discuss the classification of ATMPs as medicines and can identify who has overall responsibility for their governance and management.	Verbal	*EA*
6	Can describe procedures for secure movement of ATMP shipments into and through the hospital site.	Verbal	*EA*
7	Can describe specific location(s) for named therapeutic products to be taken to or stored in.	Verbal	*EA*
8	Can discuss the importance of maintaining the product at an appropriate temperature until it is administered.	Verbal	*EA*
9	Demonstrates thorough inspection of shipment on receipt.	Observation	*AE*
10	Can describe risk of cold burn injury, how to reduce risk and first aid procedures in event of injury.	Verbal	*EA*
11	Can discuss risk of asphyxiation, how to reduce risk and first aid procedures in event of injury.	Verbal	*EA*
12	Completion of local manual handling training within last 3 years.	Certificate	*EA*
13	Can describe how to safely move dry Shippers.	Verbal	*EA*
14	Can describe the process for returning dry Shippers to sending laboratories.	Verbal	*EA*
15	Can describe how Dry Ice should be disposed of safely and where this can be done locally.	Verbal	*N/A*

Outcome:

Has the trainee achieved the required level of competency? If certain competencies are not applicable, please explain why.	*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, but they will not need to open them or handle the therapeutic products inside.*
Please detail any further training/ re-assessments required & by what date.	*n/a*
Any additional comments.	*Competency #9 was observed by Ann Example, Cell Therapy Facility Manager:* *Ann Example 31/10/2020*

Authorisation:

Trainee		**Trainer/Assessor**	
Name	*Example Trainee*	**Name**	*Example Assessor*
Sign	*E. Trainee*	**Sign**	*Example Assessor*
Date	*01/11/2020*	**Date**	*01/11/2020*

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

Competency Assessment:
Safe use of dry Shippers and Dry Ice
Assessor guidance notes

Note: Individuals being assessed (learners) should not use this document.

These guidance notes are intended for use by training assessors.

This document provides guidance for training assessors to help determine whether learners have successfully demonstrated competencies around the safe use of dry Shippers and Dry Ice.

The **Template Checklist** should be adapted as required and completed by the assessor together with the learner to provide a written record of the assessment. A copy should be retained by the learner, and the assessor should ensure an update of training records according to local practices.

The 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.

These guidance notes provide further detail on the knowledge and skills that the learner needs to demonstrate to the assessor in order to meet the competency requirements. The level of detail in the learner's answers should be appropriate to their role and responsibilities. Some adaptation may be required according to local procedures.

No.	Requirement	Notes to assessor and expected answers	Assessment method(s)
1	Completion of safe use of low temperature transport vessels e-learning & assessment.	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, ask to see a copy of their certificate.	Certificate
2	Can describe what a dry shipper is, how it works and how it is used.	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).	Verbal
3	Can describe what Dry Ice is, how it works and how it is used.	Dry Ice is solid carbon dioxide (CO_2) in the form of blocks, slices or pellets. At normal temperatures Dry Ice sublimes (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.	Verbal
4	Has read and understood relevant risk assessments.	Local risk assessments must be in place for all work involving dry Shippers or Dry Ice. Exemplar risk assessments are available (see pages 3-14 of this document) which can be used as a basis for conducting local assessments. Ask the learner to confirm which risk assessments they have consulted.	Verbal
5	Can discuss the classification of ATMPs as medicines and can identify who has overall responsibility for their governance and management.	As ATMPs are medicines they are subject to the same requirements as for other medicinal products. 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, 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.	Verbal

No.	Requirement	Notes to assessor and expected answers	Assessment method(s)
6	Can describe procedures for secure movement of ATMP shipments into and through the hospital site.	Learner should emphasise that therapeutic products must be kept safe and secure at all times, either in the custody of suitably trained healthcare professionals or transport staff, or in a locked medicines storage area. Name the key personnel/teams as appropriate locally.	Verbal
7	Can describe specific location(s) for named therapeutic products to be taken to or stored in.	[For assessor to complete according to local arrangements (e.g. designated secure shipper storage room or designated secure freezer). If not applicable, indicate N/A on the assessment checklist.]	Verbal
8	Can discuss the importance of maintaining the product at an appropriate temperature until it is administered.	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-specific protocol.	Verbal
9	Demonstrates thorough inspection of shipment on receipt.	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.	Observation

No.	Requirement	Notes to assessor and expected answers	Assessment method(s)
10	Can describe risk of cold burn injury, how to reduce risk and first aid procedures to follow in event of injury.	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. PPE should be appropriate to the task in hand 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. 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. 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.	Verbal

No.	Requirement	Notes to assessor and expected answers	Assessment method(s)
11	Can discuss risk of asphyxiation, how to reduce risk and first aid procedures to follow in event of injury.	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 inhalation 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.	Verbal
12	Local manual handling training completed within last 3 years.	Operators should follow relevant manual handling risk assessments relating to the activities they are required to perform.	Certificate
13	Can describe how to safely move dry Shippers.	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.	Verbal
14	Describe the process for returning dry Shippers.	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.	Verbal
15	Can describe how Dry Ice should be disposed of safely and where this can be done locally.	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 sublimate (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 sublimate near to a ramp or stairwell where the CO_2 gas may become concentrated at a lower level.	Verbal

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