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The Civil Aviation Authority of Thailand

Guidance Material for Transportation of COVID-19 Vaccines

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0. Introduction

0.1 Background

In reference to Addendum No. 1 to the 2021-2022 Edition of the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions), applicable on 31 December 2020, COVID-19 vaccines containing genetically modified organisms (GMOs) or GMMOs, including those in clinical trials, are not subject to the Technical Instructions.

Engagements with the pharmaceutical industry identified that none of the vaccines developed/in development use weakened, live viruses; therefore, it is not required to address the potential classification of these vaccines as UN 3373. However, such vaccines have handling and transport requirement temperatures that may vary from -80°C and +2°C to +8°C and therefore requiring dry ice to be used as a refrigerant. The use of dry ice in large quantities on board an aircraft may raise hazards, particularly when they are transported on the main (passenger/cargo) deck of a large aeroplane. Most aircraft OEMs have provided revised information on their aircrafts' maximum capabilities to transport dry ice.

It is the operator's responsibility to assess the risks associated with the transportation of increased quantities of dry ice. In addition to dry ice, vaccines packages may contain special devices such as data loggers and cargo tracking devices that are powered mostly by lithium batteries.

For all shipments where, dry ice is used as a refrigerant for general cargo or pharmaceutical products, the shipper/operator/handler must be dangerous goods qualified, and the packing requirements must meet the applicable requirements of the Technical Instructions or the current IATA Dangerous Goods Regulations.

0.2 Purpose

The objective this Guidance Material for Transportation of COVID-19 Vaccines is to assist and provide guidelines to the entities that will participate in the movement of the COVID-19 vaccines.

0.3 Applicability

The provisions of this guidance apply to air operators, ground services provider, freight forwarders, shippers and couriers desiring to be involved in the distribution of the COVID-19 Vaccines.

0.4 Effective Date

02 April 2021

0.5 Reference

- ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) 2021-2022 Edition
- Addendum No.1 to the 2021-2022 Edition of Technical Instruction for the Safe Transport of Dangerous Goods by Air Relating to the Containment of COVID-19, 9 February 2021
- IATA Dangerous Goods Regulations (DGR) Edition 62
- Notification of the Civil Aviation Authority of Thailand on the Classification and List of Dangerous Goods which may Endanger the Safety of the Aircraft or Persons on Board the Aircraft B.E. 2562
- IATA Guidance for Vaccine and Pharmaceutical Logistics and Distribution Edition 3, 2 February 2021
- EASA Transportation of Vaccines Using Dry Ice, Guidelines in relation to the COVID-19 pandemic Issue 1, 17 December 2020

0.6 Terms and Definitions

Dangerous Goods	Articles or substances which are capable of posing a hazard to health, safety, property or the environment and which are shown in the list of dangerous goods in ICAO TI, or which are classified according to ICAO TI.
Dry ice	carbon dioxide in its solid form, a dense, snow-like substance that sublimates (passes directly into the vapour without melting) at $-78.5\text{ }^{\circ}\text{C}$ ($-109.3\text{ }^{\circ}\text{F}$), used as a refrigerant, especially during shipping of perishable products such as meats or ice cream.
Sublimation	The process of converting a solid substance (Dry Ice, Solid CO ₂) into gas (CO ₂ gas).
Unit Load Device	A unit load device (ULD) is a pallet or container used to load luggage, freight, and mail on wide-body aircraft and specific narrow-body aircraft. It allows a large quantity of cargo to be bundled into a single unit

0.7 Abbreviations

Abbreviations	Description
CAAT	The Civil Aviation Authority of Thailand
GMMOs	Genetically modified micro-organisms
GMOs	Genetically modified organisms
IATA	International Air Transport Association
IATA DGR	Dangerous Goods Regulations
ICAO	International Civil Aviation Organization
ICAO TI	ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air
ICE	Carbon dioxide solid (dry ice)
NOTOC	Notification to Pilot-in-Command
OEM	Original Equipment Manufacturer
TC/STC	Type certificate/ Supplemental type certificate
TCC	Temperature Controlled Container
ULD	Unit Load Device

1. General

1.1 Carriage of COVID-19 Vaccines

1.1.1 The COVID-19 vaccines that contain dry ice as a refrigerant, data loggers and tracking devices that are powered by lithium batteries shall comply with dangerous goods requirements as detailed in the ICAO Technical Instructions or the current IATA Dangerous Goods Regulations Manual.

1.1.2 Vaccines described under 1.1.1 shall only be transported by air operators approved to carry dangerous goods by the CAAT or by the respective foreign national authorities in case of foreign air operators.

1.1.3 All personnel involved in handling of dangerous goods (COVID-19 vaccines) shipments shall be suitably qualified commensurate with their duties, e.g. acceptance person must be qualified in Dangerous Goods Category 6.

1.1.4 Dry ice sublimates at -78°C to gaseous carbon dioxide (CO_2). Carbon dioxide is heavier than air, colour- and odourless. Carbon dioxide at low concentration (below 0.5%) has little, if any, toxicological effects. At higher concentrations ($>5\%$), it causes the development of hypercapnia and respiratory acidosis. Concentrations of more than 10% carbon dioxide may cause convulsions, coma, and death by affecting the respiratory function and causing excitation followed by depression of the central nervous system.

Consequently, dry ice is classified as dangerous goods. The use of dry ice as refrigerant raises technical and operational challenges on board of the transport-category aeroplanes. The conversion rate of dry ice to gaseous CO_2 will vary depending on package insulation, dry ice particle/pellets size, surrounding temperature, and cabin pressure.

1.1.5 As per certification specification for large aeroplanes EASA CS-25, article 25.831(b)(2) and FAA 14 CFR Part 25.831(b)(2), the carbon dioxide concentration during flight must be shown not to exceed 0.5 % by volume (sea level equivalent) in compartments normally occupied by passengers or crewmembers. For the purpose of this sub-paragraph, “sea level equivalent” refers to conditions of 25°C (77°F) temperature and 1.013.2 hPa (760 millimeters of mercury) pressure.

In case of main deck cargo compartments that are intended to be accessible during flight or the transport of cargo in the passenger compartment, the above-mentioned criterion is considered applicable.

For cargo compartments that are fully segregated from the passenger compartment and non-accessible during flight, there may be no such requirement specified in EASA CS-25 and FAA 14 CFR Part 25. However, an excessive CO₂ concentration in the specific cargo compartments, if not detected, could be unsafe for the personnel on ground (loading/unloading processes).

1.1.6 Air Operators must, based on risk-assessments and aircraft OEM information, determine aircraft capacity for the quantity limits of dry ice that can be carried safely

1.2 The Shipper Responsibilities

1.2.1 Dry ice (carbon dioxide, solid) is regulated under Article 1 of Notification of the Civil Aviation Authority of Thailand on the Classification and List of Dangerous Goods which may Endanger the Safety of the Aircraft or Persons on Board the Aircraft B.E. 2562, read with the ICAO Technical Instructions / IATA Dangerous Goods Regulations (DGR) even when used as a refrigerant for non-dangerous goods. Shippers must be dangerous goods qualified (i.e. trained and assessed) according to the training requirements in the regulations and follow the packing requirements laid out in Packing Instruction 954.

1.2.2 Dry ice must only be in packaging that allows the release of the carbon dioxide gas that is generated as the dry ice sublimates.

- a) Packaging such as aluminium, plastic or steel drums or jerricans **are not suitable**.
- b) packaging such as fibreboard or more likely expanded polystyrene boxes **are suitable** as these materials are gas permeable.

1.2.3 Dry ice can be placed directly into the appropriate packaging or in the dry ice bunker of the ULD or loose in the ULD. Completed packages can be packed with the dry ice into a larger box to form an overpack. Alternatively, the packages can be packed into a ULD with the dry ice provided that the air operator agrees. In that respect, it is not just the dry ice inside a package that can be packed into an aircraft ULD but the dry ice itself can also be in loose in the ULD. It must be emphasized that “overpack” does not exist for general cargo, and acceptance staff will consider the “overpack” of general cargo as a single package (piece).

1.2.4 Where the dry ice is in packages, the outside of each package must:

- a) be marked with the name and address of the shipper (consignor) and consignee, “UN 1845”, “Carbon dioxide, solid” or “Dry ice” and the net weight of dry ice in each package; and
- b) be labelled with a Class 9 hazard label.



Figure 1.2.4 Example of Marking and labelling

1.2.5 If the individual packages are packed with the dry ice into an overpack then the information in 1.2.4 a) and b) must be on the outside of the overpack. Where very large numbers of packages each containing dry ice are to be offered for transport, it is recommended that the shipper group packages into an overpack as this will facilitate handling and reduce the time and effort required by the airline or their ground service provider to perform the dangerous goods acceptance check.

1.2.6 There is no requirement for a Shipper's Declaration for Dangerous Goods where the dry ice is used as a refrigerant for non-dangerous goods. However, there must be information on the air waybill, or if there is no air waybill on another document, that shows: “UN 1845”, “Carbon dioxide, solid” or “Dry ice”, the number of packages and the weight of dry ice in each package.

To	By first Carrier	Routing and Destination	Air Waybill Number	Currency	CHGS Code	WT/VAL PPD/COLL	Other PPD/COLL	Declared Value for Carriage	Declared Value for Customs
Airport of Destination		Flight/Date	For Carrier Use only	Flight/Date	Amount of Insurance		INSURANCE: If Carrier offers insurance and such insurance is requested in accordance with conditions on reverse hereof, indicate amount to be insured in figures in box marked "amount of insurance".		
Handling Information									
No. of Pieces RCP	Gross Weight	kg lb	Rate Class		Chargeable Weight	Rate / Charge	Total	Nature and Quantity of Goods (incl. Dimensions or Volume)	
			Commodity Item No.						
								Vaccine UN 1845 Dry ice ____ x ____ kg.	

Figure 1.2.6 Example of Air Waybill

1.2.7 Shippers shall always make advance arrangement with the freight forwarder or directly with the air operator for the transport of shipments containing dry ice to ensure that the total weight of dry ice being offered in the consignment does not exceed the limit for the particular aircraft type. Shippers must ensure that all requirements in the ICAO TI or IATA DGR have been followed before tendering the shipment because a shipment rejection can possibly result in a delay and potentially miss the booked flight.

1.3 Air Operator's Responsibilities for Acceptance, Handling and Loading

1.3.1 The acceptance staff processing the shipments should inspect the packages, when visible, to ensure that the packaging used are designed and constructed to permit the release of carbon dioxide gas, the packages or overpacks are marked and labelled in accordance with the regulations and the details required for the completion of the air waybill, or alternative documentation, are provided by the shippers.

1.3.2 Where the consignment with the dry ice is to be stored in a freezer/cool room, there should be procedures to ensure that operator's and ground handling agent's employees are aware of the risks associated with dry ice. The carbon dioxide gas generated as dry ice sublimates displaces the air in a confined space, such as a freezer or cool room. This may create an oxygen deficient atmosphere that can asphyxiate persons. It is recommended to placard the freezer / cool room that is stored with these shipments to identify the presence of dry ice and that people should not enter the room unattended. Additional CO2 monitors that trigger alerts when the CO2 concentration exceeds the safe levels can be installed.

1.3.3 In cases where aircraft temperature controlled container (TCC) is used and in the possession of a third party (e.g. shipper, or freight forwarder), that party is responsible for ensuring the aircraft TCC is only handled by appropriately trained and qualified personnel and the serviceability of ULD is maintained.

1.3.4 Ramp Operations

Consideration must also be given to the loading and unloading of vaccines where dry ice is present as a refrigerant.

The below are minimum recommendations that should be applied:

- Verify the documentation (Load sheet, Loading Instruction Report (LIR), NOTOC) for the presence of dry ice as a refrigerant (code ICE);
- To avoid asphyxiation prior to entering an aircraft cargo compartment where dry ice is present, the cargo compartment door must be opened and allowed to vent as per the company's procedures. In absence of specific instructions, it is important to wait for a minimum of 2 minutes for ventilated cargo compartments and 10 minutes for non-ventilated cargo compartments before entering the cargo compartment;
- A visual detectable damage check should be performed to ensure there is no damage to the packaging or ULD during loading and/or offloading.

When loading and unloading boxes filled with dry ice, awareness should be raised that there can be carbon dioxide present in concentrations that potentially endanger human health. Staff engaged in the loading and unloading process should be properly trained and prepared for this.

They should be trained on the specific risks and hazards and the special procedures related to this cargo. The operator and the ground-handling provider should implement special procedures to ensure that there is no health or safety risk for the staff performing the loading and unloading of dry ice packages. In doing this, the operator and ground-handling provider should consider, as a minimum, the following:

1.3.4.1 Loading

- a. Methods to ensure that only packaging compliant with the applicable regulations is loaded on board;
- b. Procedures for reporting and addressing damaged/leaking packages.

1.3.4.2 Unloading

- a. Instructions on precautions to be taken when opening cargo or cabin doors;
- b. A second person always outside the cargo bay or cabin to monitor entrance and trigger the alarm in case of an incident;
- c. Procedures for reporting and addressing damaged/leaking packages.

1.3.4.2 Ensure proper ventilation before entering a cargo compartment containing dry ice.

1.3.4.2 Minimize ground time without ventilation.

1.3.4.2 Carry a CO2 detector when entering cargo compartments.

1.3.4.2 Develop emergency procedure in case of an incident or accident.

1.4 Loading Equipment

1.4.1 Equipment used to transport or hold temperature-sensitive healthcare shipments are critical in the overall process. Whether these are aircraft or non - aircraft containers, active or passive Temperature Controlled Containers (TCC), insulated containers, thermal blankets or ramp “cool” dollies.

1.4.1.1 Aircraft Temperature Controlled Container (TCC):

- Performance and functionalities of active / passive aircraft Temperature Controlled Containers (TCC) must be made available;
- The aircraft acceptability must be verified to ensure the aircraft TCC are allowed to be loaded aboard the intended aircraft types in accordance with the aircraft Weight and Balance Manual;
- Aircraft TCC may be very heavy due to size and total gross weight, appropriate handling equipment with the appropriate capacities (e.g. lift capacity of forklift, length of fork tines, size of pallet dolly) should be always available at all locations to avoid potential staff injury, mishandling, equipment damage and/ or service interruption;

- Training for parties who are not typically involved in aircraft ULD build-up procedures;
- Serviceability and air worthiness requirements will need to be met;
- Special handling instructions from the manufacturer of the aircraft TCC will need to be conveyed to all supply chain participants;
- Specific training programs/ requirements for the use of aircraft TCC should be in place;
- Facilitate the transport of aircraft TCC to pharmaceutical manufacturer's facility for acclimatization and loading Facilitate the immediate return of the empty aircraft TCC to allow efficient asset utilization.



Figure 1.4.1 Example Temperature Controlled Container

Note: Aircraft TCC is an aircraft container, certified or non-certified under TSO C90, with an integral temperature control system. Aircraft TCC is designed to be directly restrained by the aircraft Cargo Loading System (CLS).

1.4.1.2 Non-aircraft Temperature Controlled Containers (TCC):

Non-aircraft TCC may also be used; although non-aircraft TCCs are not aircraft ULDs, considerations on the suitable aircraft type should also be made to ensure operating limitations of the aircraft (e.g. weight and contour limits) are not exceeded as per the aircraft Weight and Balance Manual. Non-aircraft TCC may be very heavy due to their size and total gross weight, appropriate handling equipment with the appropriate capacities (e.g. lift capacity of forklift, length of fork tines, size of pallet dolly) should be always available at all locations to avoid potential staff injury, mishandling, equipment/ shipment damage and/ or service interruption. Non-aircraft TCC is also valuable reusable and returnable asset, immediate return of the empty units should be arranged to allow efficient asset utilization.

Note: Non-aircraft TCC is a non-aircraft container with an integral temperature control system. Non-aircraft TCC is usually loaded onto an aircraft pallet and restrained by a compatible aircraft pallet net.

1.4.1.3 Passive Equipment:

Other passive equipment such as thermal blankets may be used; however, their capabilities, the logistics and distribution of those items to the origin, and their return and/or their disposal of waste should be considered. The environmental impact should not be forgotten.

Facilities and equipment for the storage and handling of such equipment must be suitable. Considerations include:

- a) ULDs must not be placed on the ground. At all times ULDs must be on dollies or in storage racks;
- b) ULDs must not be lifted or moved by forklifts unless the ULD has a fork-liftable base.

1.4.1.4 Ramp “Cool” dollies

Such devices exist at some airports and can be used to help maintain temperature control while the goods are outside the temperature-controlled facility (e.g. on the ramp or outside the cargo facility).

The device capabilities should be verified as there are no specific aviation related standards beyond the basic Ground Support Equipment (GSE) aspects. The availability of such devices, at origin, destination and/or transit where they are required or desired to be used should be verified.



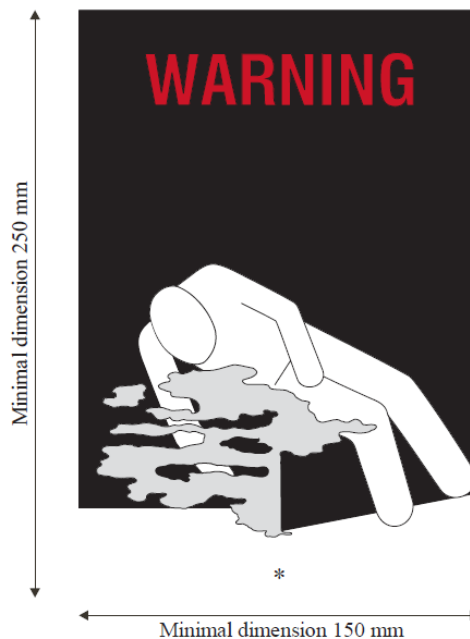
Figure 1.4.1.4 Example of Cool Dollies

1.4.1.5 Temperature Controlled Rooms / Freezers

Consideration must be given to temporary storage areas in cargo terminals such as cool rooms and freezers that are used to hold vaccines where dry ice is present as a refrigerant.

National occupational health and safety regulations must be complied with. In the absence of such regulations, below are minimum recommendations that should be applied:

- a) These storage areas present a significant asphyxiation risk from elevated CO₂ levels from sublimating dry ice. Employees that enter the cool room or freezer must be made aware that dry ice is present so that care is taken when entering the cool room / freezer.
- b) Where dry ice is present the cool room / freezer should be placarded with a warning mark affixed at each access point in a location where it will be easily seen by persons opening or entering the cool room / freezer. An example is shown below. This placard should remain on the cool room / freezer until the following provisions are met:
 - I. the cool room / freezer has been ventilated to remove harmful concentrations of CO₂; and
 - II. the packages containing the dry ice have been removed.



*Figure 4.3.1.5: Asphyxiation Warning Mark
 (UN Model Regulations, 21st revised edition, Figure 5.5.2)*

* Insert “DRY ICE” or “CARBON DIOXIDE, SOLID” in letters at least 25 mm high.

Other mitigation actions could include the installation of CO₂ monitors / alarms in the cool room / freezer.

2. Dedicated Risk Assessment

For the transport of vaccines using dry ice in excess of the limit specified in the operations manual or other applicable documents (e.g. aircraft TCH/OEM Service Letter or similar), the operator should perform a specific risk assessment. Such risk assessment may require getting in contact with the type certificate or supplemental type certificate (TC and/or STC holder) and should propose appropriate operating procedures in order to adequately mitigate the identified risks. This risk assessment should at least cover:

- 2.1 The vaccine and its characteristics for transport as cargo (i.e. packaging, handling, etc);
- 2.2 The data trackers and loggers
- 2.3 The amount and effects of dry ice to be carried (including weight and balance considerations) and the associated sublimation rate with validation of the assumed rates vs. all operational scenarios.
- 2.4 The possible need for CO₂ detectors to mitigate the identified risks;
- 2.5 If applicable, the aircraft ventilation system's operational characteristics, performance, controls, selections-settings in all operational procedures for normal/ abnormal/ emergency operational scenarios and phases of operation (including applicable MEL provisions);
- 2.6 All other relevant aircraft and systems configurations (including applicable MEL provisions);
- 2.7 The location of the cargo on board and the interaction with other cargo;
- 2.8 The aircraft occupancy (whether occupants are allowed on board or not);
- 2.9 The procedures and training of on-board occupants, ground handling and other relevant staff;
- 2.10 The analysis of ambient temperatures on the ground (at departure and arrival), which may lead to a higher sublimation rate (particularly when flying to warm areas);
- 2.11 The potential pressure build-up as a result of gas released from the packaging;
- 2.12 The impact of potential departure delays, extended taxi-in/out and additional time needed on the ground (e.g. for de-icing);
- 2.13 The consequences of diversion and specific airport ground-handling consideration;
- 2.14 The possible diversion times and the need to use alternative routes where necessary;
- 2.15 The extended loading time needed in case of transport in the passenger cabin, which may result in excessive CO₂ concentration.

The risk assessment should ensure that all relevant technical and operational aspects have been taken into account.

The operators need to perform a risk assessment which includes the specificities of dangerous goods transport (as from November 2020, ICAO Annex 6, Chapter 15 also calls for such a risk assessment). Additional guidance contained in ICAO Doc 10102 may also be considered. The table 2-1 “Requirement for Carriage of Quantities of Dry Ice in Excess of that Previously Specified by Operator for the Aircraft Type” show the transportation of COVID-19 vaccines specific risk assessment.

To ensure the transport is done safely, operators transporting quantities of dry ice in excess of that specified in the operations manual or other applicable documents (e.g. OEM/TCH Service Letter or equivalent) should consider additional mitigation actions. The training, procedures and risk assessment mentioned above must take into consideration the specific conditions of this transport. These must also include all the technical considerations mentioned before and apply to all the staff involved and all the stages of the operation, from the acceptance to the unloading.

The operator may additionally consider the following:

- Lower the temperature in the cargo compartment as much as possible to minimize the sublimation rate;
- Evaluate the potential for cargo containing dry ice to be loaded as late as possible and unloaded as early as possible to minimize the potential exposure of ground staff to elevated levels of CO₂ in the cargo compartment.

Table 2-1 Requirement for Carriage of Quantities of Dry Ice in Excess of that Previously Specified by Operator for the Aircraft Type	
Hazard Description	Information to Support Hazard Assessment
a) hazards associated with the properties of the items to be transported;	
Carriage of large quantities of dry ice (CO ₂ , solid)	<ul style="list-style-type: none"> - The sublimation of dry ice may result in significant concentrations of gaseous CO₂ in aircraft - Gaseous CO₂ will replace oxygen in aircraft compartments and may interfere with the breathing abilities of the occupants - High concentrations of CO₂ can lead to unrecognized degradation of cognitive functioning and asphyxiation. It causes suffocation by displacing and diluting the amount of oxygen in the air, leading to hypoxia (lack of oxygen) and is toxic to brain functioning
b) capabilities of the operator	
	<ul style="list-style-type: none"> - Operators must ensure that their dangerous goods training programme, operational procedures and safety management system address the requirements applicable to transport of dry-ice (including the acceptance, handling, loading and carriage of cargo containing dry ice) during both ground and flight operations. - Pilot and crew training on specific conditions and procedures can improve pilot decision-making in the event of a CO₂ detector alert or other system abnormalities - Training for loading and unloading precautions for ground/ service crews
c) operational considerations;	
	<ul style="list-style-type: none"> - The operators' determination of the maximum amount of dry ice it will allow in a cargo compartment based on the aircraft manufacturer's recommendations, operational considerations for the air conditioning system, and the sublimation rate. - An accurate determination of the dry ice sublimation rate is necessary to determine the quantity of dry ice that may be safely transported - Sublimation rate can be affected by ambient compartment temperature and pressure, amount of insulation surrounding the dry ice, type of container, amount of surface area of the dry ice, and the temperature of the cargo being cooled by the dry ice - As the dry ice sublimates, a loss of weight occurs that may affect the aircraft center of gravity - CO₂ sensors installed or carried in the aircraft to recognize hazardous concentrations of CO₂ and to implement effective risk controls

Table 2-1 Requirement for Carriage of Quantities of Dry Ice in Excess of that Previously Specified by Operator for the Aircraft Type	
Hazard Description	Information to Support Hazard Assessment
	<ul style="list-style-type: none"> - Aircraft ventilation during normal procedures, to include engine start, less than all engine taxi, aircraft de-icing, and with MEL deferred items - Aircraft ventilation during abnormal and emergency procedures to include abnormal and emergency operations and flight during air system component failure.
d) capabilities of the aircraft and its systems;	
	<ul style="list-style-type: none"> - The environmental control system on the aircraft must be suitable for the quantity of dry ice intended to be carried, including flow mode, air recirculation control, MEL deferred items, and possible malfunctions en-route - Additional guidance specific to each aircraft types and models, if any, should be obtained from the aircraft manufacturer.
e) containment characteristics of unit load devices;	
	- None
f) packing and packaging;	
	- Compliance with packing requirements detailed in the Technical Instructions
g) safety of the supply chain for items to be transported;	
	- None
h) quantity and distribution of dangerous goods items to be transported	
	- As determined by the operators' safety risk assessment taking into considerations of items a) to g)

3. Technical Considerations – Safety of Flight

Vaccines cooled by dry ice should preferably be transported in the existing lower-deck cargo compartments. In case vaccines, cooled by dry ice, need to be transported on the main (passenger/cargo) deck, additional technical aspects should be considered.

3.1 Ventilation and Pressurisation System

a) MEL considerations

For aircraft dispatch, the air conditioning, air supply and the distribution/ventilation system should use configurations recommended by the manufacturer.

b) AFM considerations

The AFM procedures for ventilation should be reviewed and adapted in the operator's standard operating procedures to consider carriage of dry ice under normal and failure cases.

To mitigate the risk of higher concentrations of CO₂ (above 0.5%), it is recommended that the ventilation and pressurisation system is fully operational, i.e. all air-conditioning packs should be running at all times.

In case of partial failure of the ventilation system in flight, the situation has to be carefully evaluated in order to decide if the flight may continue to destination. The OEM guidance should account for a single next critical failure to enable continuation of the flight, while total failure of the ventilation system in flight should lead to an immediate diversion to the nearest suitable airport.

Note 1: Running the air-conditioning systems at maximum volume may lead to an additional risk when opening the doors due to potential residual overpressure. The operator should consider this hazard when drafting the operational procedures for the transportation of vaccines.

Note 2: The operator should consider the case of build-up of CO₂ concentration in the cabin as a possible emergency situation and should develop a procedure to require the donning of oxygen masks for the remaining duration of the flight.

3.2 Oxygen System

a) MEL considerations

For aircraft dispatch the crew oxygen systems should be fully operative.

b) AFM considerations

The AFM procedures for the use of oxygen should be reviewed and adapted in the Operator Standard Operating Procedures to consider carriage of dry ice under normal and failure cases (e.g. failure of the ventilation systems), including the case of detection of dangerous concentration of CO₂ (if applicable).

3.3 CO₂ Detectors

Based on the risk assessment (see chapter 2.4), the operator should determine whether CO₂ detectors should be used for the flight deck and any other occupied area of the aircraft (e.g. passenger cabin).

If the amounts of dry ice to be transported (refer to aircraft OEM specifications, supplier packaging details and other guidance material) is in excess of that specified in the operations manual or other relevant manuals and in the guidance provided by the OEM, or if dry ice is loaded on the main (passenger/cargo) deck, the use of CO₂ monitors/detectors is recommended in all compartments in which dry ice is being transported. Such detectors should be adequately located and should timely and reliably detect dangerous concentrations of CO₂ in the aircraft. If the detectors are power supplied by lithium ion batteries, the additional fire risk must be assessed and mitigated accordingly.

Note: “Use” in this context means physically installed in the aircraft or alternatively portable devices. If CO₂ sensors and monitoring systems are used, the operator should ensure that these devices do not interfere with the aircraft systems and do not affect the safe operation of the aircraft. Portable CO₂ detectors are considered Portable Electronic Devices (PED). Recent/frequent calibration of CO₂ detectors must be ensured. At least two sensors should be available in case of a sensor disagree.

3.4 Loading Locations

3.4.1 Lower and Main Deck Cargo Compartments

Vaccines cooled with dry ice should preferably be transported in lower-deck cargo compartments. It is recommended to use the cargo compartment that is located to the next outflow valve, in order to effectively ensure that even in the case of partial or complete failure of the ventilation and pressurisation system during flight, the CO₂ will be ventilated overboard.

3.4.2 Passenger Cabin

CAAT published specific conditions for the potential transportation of cargo in passenger compartments (*CAAT - Guidelines for the Transport of Cargo in the Passenger Compartment*). A minimum number of occupants should be onboard for fire detection and fire-fighting purposes. Vaccines cooled with dry ice may be transported in the passenger cabin when the associated risks are sufficiently mitigated. Details are addressed below in chapters 3.5 and 3.6.

3.5 Occupants on Board (Their Roles and Location, Equipment, etc.)

3.5.1 Flight crew:

The operator should take all necessary steps to avoid that the flight crew is harmed by carbon dioxide incapacitation or intoxication.

Flight crews should have been properly trained prior to the flight on the hazards and risks of transporting dry ice and on the procedures related to the operation.

3.5.2 Other occupants:

Passengers should not be allowed onboard if dry ice is transported in excess of the limit specified in the operations manual or other applicable documents (e.g. aircraft TCH/OEM Service Letter or similar). Any other occupants onboard should only be allowed if required under demonstrated urgent operational needs (e.g., additional flight crew for the return flight or additional persons needed for the cargo handling).

If occupants, that are not considered flight crew, need to be onboard, they should be protected against a potential CO₂ intoxication by the following means:

- (1) Have access during all phases of flight to approved supplemental oxygen equipment ready to be used.
- (2) Have been properly trained prior to the flight on the use of that oxygen equipment.
- (3) Have been properly trained prior to the flight on the hazards and risks of transporting dry ice and on the procedures related to the operation. And
- (4) In addition, CO₂ detectors should be available in the cabin (see 3.3).

Any seating position identified for a potential occupancy during any phase of the flight should pose no additional risk to its occupants, in particular in case of a CO₂ incapacitation/intoxication

3.6 Segregation with Other Cargo

Live animals may not be transported in cargo compartments if dry ice is also transported therein at the same time. Any interaction with other cargo should be assessed and mitigated by the air operator and the shipper.

4. Dangerous Goods Specific Considerations - Lithium Batteries

4.1 Where lithium battery-powered data loggers / cargo tracking devices are used or have been installed in the shipments, the shipper / air operator must ensure that the applicable provisions in the ICAO TI or IATA DGR are complied with. These include:

- a) Obtaining a copy of the lithium battery test summary from the manufacturer / supplier of the lithium batteries or the manufacturer / supplier of the device. This test summary must confirm that the lithium cell or battery type has passed all applicable tests in Subsection 38.3 of the UN Manual of Tests and Criteria.
- b) Packing requirements laid out in Section II of Packing Instruction 967 or Packing Instruction 970 in the ICAO TI or IATA DGR, as applicable.
- c) Unless the data logger / cargo tracking device only contains a button cell, then where there are:
 - I. more than two packages in the consignment that contain a data logger / cargo tracking device in each package, or
 - II. multiple data loggers / tracking devices in a package (e.g. more than four devices powered by lithium cells or more than two devices powered by lithium batteries)
 - III. then each package should bear the lithium battery mark with “UN 3481” or “UN 3091” as applicable, and there should be a compliance statement on the air waybill, when an air waybill is used.
- d) All employees preparing or offering shipments must receive adequate instruction on the provisions set out in the aforementioned packing instructions. This adequate instruction must be commensurate with the functions for which they are responsible.

Note: In order to speed up the transport process, the requirement for the lithium battery mark on packages containing COVID-19 vaccines accompanied by data loggers and/or cargo tracking devices containing lithium batteries is removed by ICAO.

4.2 Some data loggers / cargo tracking devices may not be powered by lithium batteries but other battery types, such as dry batteries or nickel-metal hydride batteries that are not restricted by the ICAO TI or IATA DGR when the conditions as shown in the corresponding special provision in the ICAO TI or IATA DGR are met (e.g. Special Provision A123 for dry battery and Special Provision A199).

- 4.3 Where the data loggers / cargo tracking devices are a type with transmitting functions, the shipper must ensure that:
- I. They confirm with the manufacturer / supplier of the device that the device has passed all applicable tests to ensure that it does not pose a hazard to aircraft systems due to emission of electromagnetic radiation.
 - II. The device is fitted with two independent means of shutting down all transmitting functions when airborne.
 - III. The device has been approved by the airline on which the cargo will be transported.
- 4.4 All other dangerous goods acceptance, verification checks, documentation processes shall be in accordance with the operator's approved dangerous goods procedures manual.