CIVIL AVIATION AUTHORITY OF NEPAL

COVID-19 Vaccine Carriage Circular 09/2021			
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1. BACKGROUND

The global health pandemic caused by COVID19 has also affected Nepal and Government of Nepal has taken proactive measures to control spread of virus in Nepal. The world community is working towards development of vaccine against the vaccine and some of the are already developed and tested. Some of them are already in position of deployment. At this critical moment, Civil Aviation Authority of Nepal is aware of the need of transportation vaccine for virus by air which may require certain alleviation with regard to carriage of dangerous goods by air. Since these vaccines will have short life and need to be transported with maximum precautions maintaining cold chain- there will be high demand of air transportation in coming days. Globally, it is believed that aircrafts with fewer number of passengers to transport may be utilized to transport these vaccines from one place to another. Hence, these guidelines are prepared to safely transport them and to comply with the existing directives, standards and recommendations practices and requirements of Annex-18 and Doc 9284 of ICAO and DGHR of CAAN. CAAN is in regular contact with ICAO and various regulatory authorities for the development of this guidance material.

2. OBJECTIVE

Worldwide demand for COVID-19 vaccines will result in a significant increase in the volume of vaccines offered for air transport. The purpose of this guidance is to identify the specific areas related to the air transport of vaccines that may require action by the operator and regulator to facilitate the safe air transport of vaccines.

3. REGULATORY CONSIDERATION

3.1 It is understood that by complying with the requirements of Annexes 6, 18, 19 and the *Technical Instructions for the Safe Transport of Dangerous Goods by Air* (Doc 9284, Technical Instructions) and subsequent Nepalese standards in FOR, DGHR and CAR 19, operators will be able to safely accept, handle and transport these vaccines.

3.2 The transport of vaccines must comply with the detailed provisions of the Technical Instructions where the vaccines are classified as dangerous goods, or the vaccines are shipped with dry ice as a refrigerant, or data loggers and cargo tracking devices are included in packages or attached to packages or overpacks.

3.3 The UN Sub-Committee of Experts of the Transport of Dangerous Goods (57th session) confirmed that genetically modified micro-organisms based vaccines authorized for use (including clinical trials) are not subject to the UN model regulations for transport. As a result, ICAO is currently reviewing the applicability of the Technical Instructions to genetically modified vaccines and will be issuing advice through a State letter shortly. As such this issue has not been addressed in the following guidance.

3.4 Changes to the Technical Instructions (TIs) to remove some of the normal marking requirements for packages containing vaccines and lithium batteries contained in equipment are being considered by ICAO. If and when these changes are approved in ICAO, any hazards and risks associated with the change may need to be mitigated by other means. Further information will be provided below in the event of this change being approved.

3.5 Chapter 15 to Annex 6, Part I and Flight Operations Requirements-Aeroplane require a risk-based assessment, in addition to the prescriptive requirements in the Technical Instructions, for operators transporting items in the cargo compartment. The elements of the safety risk assessment set out in Chapter 15 to Annex 6, Part I and Flight Operations Requirements-Aeroplane have been used as the basis for reviewing the changes proposed to the existing requirements to determine what additional risk mitigations may need to be implemented.

4. KEY CONSIDERATION

The following key issues have been identified in relation to the carriage of COVID-19 vaccines.

4.1 Data loggers and cargo tracking devices (batteries & quantities)

Data loggers and cargo tracking devices may be required to monitor the temperature and location of vaccines during transport. Most such devices are powered by lithium batteries and the packages need to be properly identified as such. The following table identifies the hazards associated with the data loggers and trackers transported, and the considerations for the operators' risk assessments. (Details in Appendix-1)

4.2. Data loggers and cargo tracking devices (EMI)

Inclusion of transmitting/receiving devices in packages for the purposes of tracking and data logging (e.g. of temperature) has the potential for electromagnetic interference with aircraft systems. The potential risk to the operations needs to be assessed.

4.3. Requirement for carriage of quantities of dry ice in excess of that previously specified by operator for the aircraft type.

4.4 At present, many of the vaccines need to be transported in temperature controlled conditions. These conditions are specific to the vaccine itself. For example, some of the vaccines need to be kept at temperatures that require dry ice (carbon dioxide, solid) for cooling purposes. The volume of vaccine to be transported means that the quantity of dry ice proposed for carriage exceeds that previously specified for the aircraft type in the operator's manuals. A review of the risk assessment based on the considerations provided may be needed.

5. GUIDANCE TO SUPPORT RISK ASSESSMENT PROCESS

5.1 The associated guidance for both the air operator and the regulator to facilitate a common understanding of the requirements can be found at ICAO website at link Safe transport of COVID-19 vaccines on commercial aircraft (icao.int). It is structured around each element the operator is required to consider as part of its specific safety risk assessment and based on Guidance for Safe Operations Involving Aeroplane Cargo Compartments (Doc 10102). However, where the vaccine supply chain requires use of smaller aircraft without cargo compartments, this material can still be used as some guidance to develop the associated risk assessments for these types of operations. Different mitigation strategies may need to be developed depending upon the type of aircraft and operation considered.

5.2 Packages of vaccines may contain multiple elements such as:

- the vaccine component itself;
- data loggers and cargo tracking devices powered by lithium batteries, and that emit electromagnetic radiation that have the potential to interfere with aircraft systems; and
- dry ice.

5.3 For each identified element in the package, the following considerations will need to be addressed, to maintain safe operations.

5.4 Further guidance on safety risk management can be found in Chapter 2.5 of the Safety Management Manual (4th edition) and associated CAAN SMS implementation Guide.

6. TECHNICAL CONSIDERATION

6.1The temperature maintenance requirement for COVID-19 vaccines is reported to be varying from -8° C to -70° C and hence, the use of refrigerant material during the transportation becomes essential. Though there may be different refrigerant options, use of dry ice (Carbon Dioxide Solid) is the most commonly used, affordable and readily available refrigerant material available in the country for transportation of perishables by air.

6.2 Dry Ice continually sublimates (Dry ice that is solid, transforms into Carbon Dioxide gas (CO_2) at temperatures higher than -78° C(-108.4°F) under normal atmospheric pressure. At reduced pressures, the sublimation rate of dry ice will increase while all other factors being the same. Hence, ICAO under Annex 18 and Doc 9284- Technical Instructions that governs safe transportation of dangerous goods by air has classified dry ice as Class 9- Miscellaneous dangerous goods.

7. OPERATOR'S RESPONSIBILITY

All operators while engaging in transportation of COVID-19 Vaccines packed with dry ice shall establish the maximum quantity of dry ice that can be loaded in a given cargo hold and/ or compartment or in the main deck (passenger cabin) when a passenger version aircraft is deployed for all cargo operations. This maximum quantity shall be based on the aircraft manufacturers' information on maximum recommended dry ice quantities that the aircraft ventilation can support, depending on the sublimination rate and also the requirements of the operators' Safety Management Systems.

7.1 Carriage of Dry ice in cargo compartment:

For the transport of vaccines in dry ice in excess of the limit specified in the Operations Manual, Dangerous Goods Manual or other applicable aircrafts manufacturer documents, the operator should perform a specific risk assessment. Such risk assessment may require getting in contact with the 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:

a) The vaccine and its characteristics for transport as cargo (i.e. packaging, handling etc.);
b) 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;
c) The possible need for CO_2 detectors to mitigate the identified risks;
d) 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);
e) All other relevant aircraft and systems configurations (including applicable MEL provisions);
f) The location of the cargo on board and the interaction with other cargo;
g) The aircraft occupancy (whether occupants are allowed on board or not);
h) The procedures and training on on-board-occupants, ground handling and other relevant staff;
i) The analysis of ambient temperatures on ground (at departure and arrival), which may lead to a higher sublimation rate (particularly when flying to warm areas);
j) The potential pressure build-up as a result of gas released from the packaging;
k) The impact of potential departure delays, extended taxi-in/out and additional time needed on the ground (e.g. for de-icing);
l) The consequences of diversion and specific airport ground-handling consideration;
m) The possible diversion times and the need to use alternate routes where necessary; and
n) The extended loading time needed in case of transport in the passenger cabin, which may result in excessive CO_2 concentration.

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

7.2 Carriage of Dry ice in passenger cabin:
Vaccine packed in dry ice should preferably be transported in lower-deck cargo compartments. However, in case Operators desire to carry vaccines packed in dry ice in the passenger cabin, in addition to para 3.1 , the following shall be complied with:
7.2.1 Occupants on board:

(1) Flight crew:
   (a) The operator should take all necessary steps to ensure that the flight crew is not harmed by CO_2 incapacitation or intoxication.
   (b) Flight crew should be properly trained on the hazards and risks of transporting dry ice and on the procedures related to the operation.

(2) Other occupants:
   (a) Passengers shall not be allowed on-board.
   (b) Any other occupants on-board 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).
   (c) Occupants, that are not considered flight crew, should be protected against a potential CO_2 intoxication by the following means:
      (i) Have access during all phases of flight to approved supplemental oxygen equipment ready to be used.
      (ii) Have been properly trained on the use of oxygen equipment.
      (iii) Have been properly trained on the hazards and risks of transporting dry ice and on the procedures related to the operation.

(3) Adequate number of CO_2 detectors should be available in the cabin. Such detectors should be located at locations for timely and reliable detection of dangerous concentrations of CO_2 in the aircraft. If the detectors are power supplied by lithium ion batteries, the additional fire risk must be assessed and mitigated accordingly.

8.AIRCRAFT TECHNICAL CONSIDERATIONS

Following aircraft technical consideration should be taken into account by the air operator.

8.1Aircraft ventilation and Pressurization System-

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

AFM consideration- 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.
The operator's standard operating procedures should also include lowering to temperature in the cargo compartment as much as possible to minimize the sublimation rate of dry ice.
To mitigate the risk of higher concentrations of CO_2, the ventilation and pressurization system shall be 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.

8.2 Aircraft Oxygen System

Following factors should be taken into consideration for the aircraft system.

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

AFM consideration- 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 CO_2 (if applicable)

It is recommended to use the cargo compartment that is located next to the outflow valve, in order to effectively ensure that even in the case of partial or complete failure of the ventilation and pressurization system during flight, the CO_2 will be ventilated overboard.

9.PACKAGING AND HANDLING

The air operators have to follow following procedures for Packaging and Handling.

9.1 Ensure that the shipments containing COVID-19 vaccines packed in dry ice shall be accepted and handled by appropriately trained personnel only.

9.2 Prepare a "Dos & Don't" guidance and circulate among those handling personnel the specific requirements that may be applicable for handling shipments containing COVID-19 vaccines packed in dry ice considering the sensitivity of the shipments and also possibility of large quantities of dry ice required to be handled.

9.3 Adequate precautions need to be taken at the end of flight, as compartments or ULDs containing dry ice will tend to have high concentration of CO_2 and also the area immediately outside the door experiences high concentration CO_2 for several minutes.

9.4 The "Dos & Don't" should cover at least the following:

(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.
(2) Unloading:
   (a) Instructions on precautions to be taken while opening of cargo or cabin doors;
   (b) A second person shall always be available outside the cargo bay or cabin to trigger the alarm in case of any unforeseen event;
   (c) Procedures for reporting and addressing damaged/leaking packages.
(3) Ensure proper ventilation before entering a cargo compartment containing dry ice.
(4) Minimize ground time without ventilation.
(5) Carry a CO_2 detector when entering cargo compartments.
(6) Develop emergency procedures in case of an incident or accident.
(7) Evaluate the potential for cargo containing dry ice to be loaded as late as possible and unloaded as early as possible.

9.5 Confirm that the packages containing dry ice are packed, marked, labelled and documented meeting the requirements of ICAO Annex 18 and Doc 9284- Technical Instructions for Safe Transportation of Dangerous Goods by Air.

9.6 Ensure that each package containing COVID-19 vaccines packed in dry ice is clearly marked- DRY ICE or CARBON DIOXIDE SOLID and specifies the net quantity contained in each package.

Ensure that the Shipper provides a packing list clearly indicating-

a. Package Identification Number
b. Gross Weight of the package
c. Net Quantity of dry ice contained in the package
d. Total Gross Weight and total Net Quantity of dry ice of the consignment

9.7 Ensure that the ULDs (Pallets/ Containers) that are loaded with COVID-19 vaccines packed in dry ice are provided with placard clearly indicating -Dry ICE or CARBON DIOXIDE SOLID and net quantity contained in each ULD;

9.8 Use acceptance Checklist of dry ice when Shippers Declaration for Dangerous Goods (DGD) is not required while accepting shipment of COVID-19 vaccine packed in dry ice:

(i) Follow the general compatibility, loading and securing requirements as detailed in the ICAO Annex 18 and Doc 9284 – Technical Instructions.
However, considering the high volume of dry ice and sensitivity of the contents, as a matter of extraordinary precaution and with a view to avoid possible contaminations of the external surfaces of the packages and or the contents therein, no other goods such as foods, meat, fish, flowers, vegetables, fruits, live animals, etc. shall be loaded adjacent to these packages in the same compartment or cargo hold of the aircraft.

(ii) Inform the Pilot-in-command in writing of the quantity of dry ice loaded including loading locations.

10. ADDITIONAL GUIDANCE

The air operators are encouraged to refer additional guidance issued by IATA and respective aircraft manufacture in these regards.

11. ISSUING AUTHORITY

Director General
Civil Aviation Authority of Nepal

12. CONTACT OFFICE

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