

P12

Shipper's Declaration

E356 – Pharmaceutical and Bio-Chem Supply Chain

Diploma in Supply Chain Management

E356 Topic Tree



Pharmaceutical and Bio-chem Supply Chain

- Introduction to Pharma and Bio-chem
- Classification of Dangerous Goods
- Best Practices (GMP/GDP)
- Clinical Supply Chain
- Cold Chain Management

Import, Packaging and Distribution

- Import and Distribution of Medical Devices
- Import of Pharmaceutical and Bio-Chem Products
- Local Transportation of Pharmaceutical and Bio-Chem Products
- Packaging of Pharmaceutical DG for Air Transport
- **Declaration of Pharmaceutical DG for Air Transport**

Product Tracing, Recall and Disposal

- Product Tracing (anti-counterfeit technologies)
- Drug Recall
- Disposal of Bio-chem Products in Hospital Logistics



Recap - Key Steps for shipping DG

1. **Classification:** Material being shipped must be categorized as a type of hazardous material
2. **Identification:** The shipper selects the proper shipping information from the IATA Dangerous Goods Regulations
3. **Packaging:** Properly packing the hazardous material for shipment
4. **Marking:** Writing the followings on the package: address, shipping name of hazardous material and UN code
5. **Labelling:** Identify the package as possessing a hazardous material and give a general indication of the type of material
6. **Documenting:** Filling in and signing the AWB and shipper's declaration



Dangerous Goods Regulation (DGR)

- The DGR is in consultation and based on ICAO Technical Reference as an easy to use guidance for shipping DG via air. It incorporates the additional requirements that the various airlines impose as additional requirements when shipping the DG.
- The DGR manual is divided into **10** main sections, followed by 8 Appendices and is published every year, with changes to previous year stated in the introduction pages of the manual.
- Version 61th edition is valid for use from 1 Jan 2020 to 31 Dec 2020





Overview of DGR Manual

- **Section 1 – Applicability**
- **Section 2 – Limitations**
- **Section 3 – Classifications**
- **Section 4 – Identifications**
- **Section 5 – Packing**
- **Section 6 – Packaging Specifications and Performance Tests**
- **Section 7 – Marking and Labelling**
- **Section 8 – Documentation**
- **Section 9 – Handling**
- **Section 10 – Radioactive Material**
- **Appendices A , B, C, D, E, F, H and I**

DGR Section 1- Applicability



- It covers the **definitions** used, the **responsibilities of operators** (airlines) and **shippers, training requirements, and security** aspects for handling DG.
- The shipper is responsible to properly prepare (i.e. identification, classification, packing, marking, labeling and documenting) a shipment of DG for transport by air.
- The operator is responsible to ensure, as far as possible, that the consignment has been prepared in accordance with the Regulations
- Training Requirements – Training must be provided or verified upon the employment of personnel identified in the categories specified in *DGR Table 1.5A*. Recurrent training must take place with 24 months of previous training to ensure knowledge is current. A test must be undertaken following DG training to verify understanding of the regulations.





DGR Section 2- Limitations

- **Why is this section important?**
 - This section is important as it specifies the various limitations (including limitation imposed by State /Country and Operator/ Airlines), forbidden DG, hidden DG and provisions for DG carried by passengers or crew.
 - Different country and airline operator can have varied **limitations** and provisions on **Variations**. It is therefore important to refer to the State and Operator variation when preparing to ship the DG
 - Check **2.8.2** for the Variations by state
 - Check **2.8.4** for the Variations by Operator



DGR Section 2- Limitations



- **Examples of limitation under 2.8.4:**
 - SQ-05 Only Division 6.2, Class 7 and Class 9 will be uplifted into/over the United States in a passenger aircraft.
 - SQ-10 Carriage of Category B infectious substances, UN3373 – Biological substance Category B is subjected to specific requirements. Shipper wishing to consign UN3373 are requested to contact the Singapore Airlines Cargo office for these requirements.





DGR Section 3 - Classifications

- It provides in detail the **criteria used** to determine which class/division the substance fall under.
- **3.6.2. is important for shipping division 6.2 as it is used to classify Category A and B, and Exceptions.**
 - E.g. 3.6.2.2.3.5 Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests and blood or blood components or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subjected to these regulations.
- **Table 3.6.D** is the list of all micro-organism in **Category A** is in this section of the DGR.

Infectious Substance
Affecting Humans
UN 2814

Fill in the specific name of the infectious agent and specimen type below (do not include volume of specimens other than infectious)

Name of infectious agent:

Specimen type:
Blood/plasma/serum ☐
Other ☐

Volume of infectious material: ml

If volume is greater than 60 ml, attach "Cargo - Do Not Load in Passenger Aircraft" (see 3.6.2.2.3.5)

Infectious Substance, Affecting Humans
IN CASE OF DAMAGE OR LEAKAGE
IMMEDIATELY NOTIFY
PUBLIC HEALTH AUTHORITY
IN U.S.A.
NOTIFY DIRECTOR - CDC
ATLANTA, GA
1-800-328-6438

6

4G/Class 6.2/07
USA/+AA4447

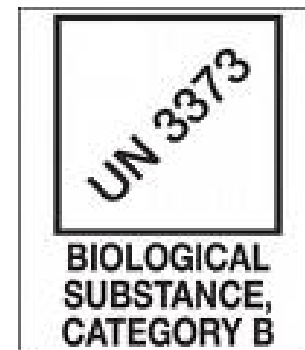
RE1208 (Rev06/05)





DGR Section 4 - Identifications

- This is the main section that states and defines the UN number, hazard class, sub risk, packing group, excepted quantity shipping (where available), the various applicable Packing Instructions, Special Provisions, and Emergency Response Drill Codes for the specific substance defined by its proper shipping name.
 - E.g. UN2900, UN2814, UN3291 and UN3373
- Section 4.3 is used for cross reference when you know the UN number but not sure about the proper shipping name.





DGR Section 5 - Packing

- All the packing instructions details defined in section 4 are available in section 5 here.

For example:

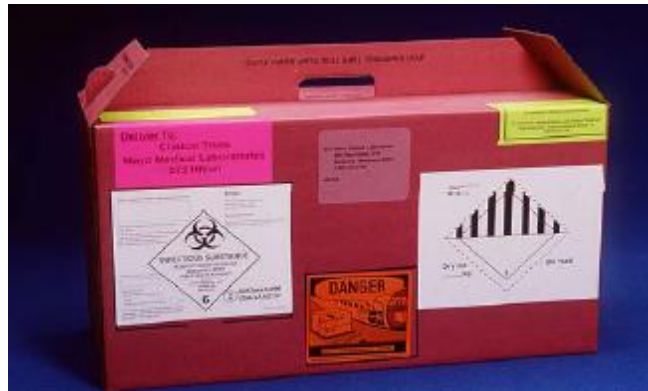
- State and operator variations that are applicable
- The UN number that the Packing instruction is used for.
- All the requirements like special marking and labeling





DGR - Section 6, 7

- **Section 6 – Packaging Specifications and Performance Tests**
 - This section defines what is needed to get the UN marking approval for packaging to be used in DG shipping.
- **Section 7 – Marking and Labelling**
 - This section defines the specifics of marking and labeling for DGR.



DGR Section 8 - Documentation



- This section specifies the requirements for filling up a **“Shipper’s Declaration for Dangerous Goods”**.
- Information from the prior sections are read off and used in filling up the information in the DGD form.
- Only minor discrepancies like commas and dots stops are accepted.
- Airlines will turn away shipment with any errors in the declaration form with the exception of “minor errors” mentioned above.
- Alterations must all be signed by shipper, except airway bill, airport of departure and destination.
- **For UN3373, the shipper declaration is not needed.**

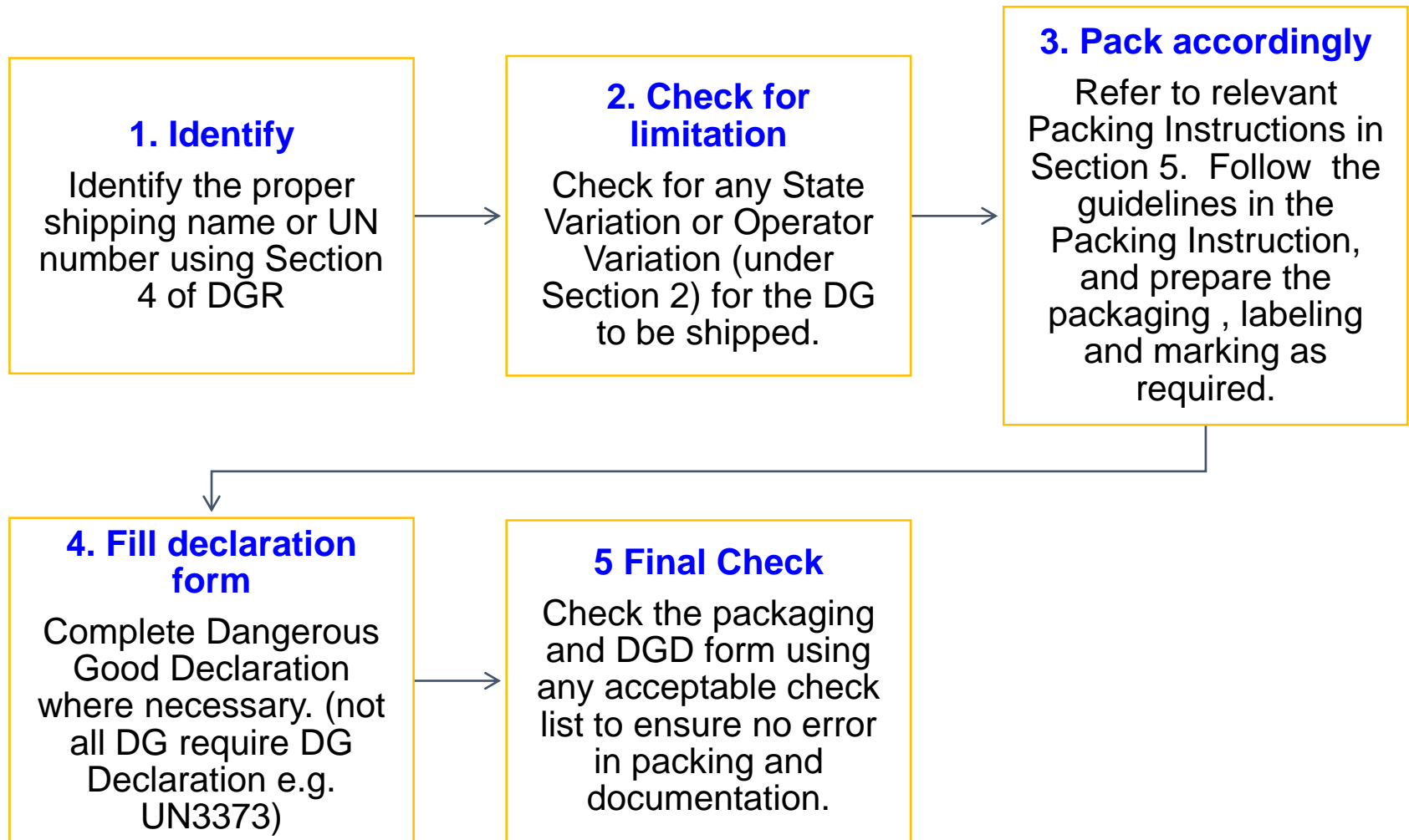


Dangerous Goods Declaration (DGD)



- Only **Originals** are accepted.
- DGD has to be done in English.
- Two copies to be tendered for each flight (i.e. a route transporting DG that requires a 1 flight change over would require up to 4 copies) unless otherwise required by specific operators/ airlines.
- All amendments must be endorsed and signed against by the shipper. The signature must be same as used in document.
- Omission of dots and commas are the only discrepancies accepted.
- **Only abbreviation and symbols in DGR Appendix B are accepted.**
- Only **THREE (3)** places (see below) in the Declaration can be amended by any person other than the shipper.
 - 1) Air Waybill Number
 - 2) Airport of Departure
 - 3) Airport of Destination

Steps to ship DG by Air





Problem Solution

1) 40 ml of Ebola, is classified as Category A infectious substance, hence declaration is required.

2) 1.8 litres of blood sample infected with Coronavirus, is classified as Category B infectious substance, hence declaration is NOT required.

Decisions to Classify a Substances as Category A :

Note:

If there is doubt as to whether or not a substance meets the criteria of Category A, it must be included in Category A



Problem Solution

SHIPPER'S DECLARATION FOR DANGEROUS GOODS	
Shipper Kenny Lim SG Diseases Research Pte. Ltd. Science Park II 21 Science Park Road Singapore 117525	Air Waybill No. 234533567 Page 1 of 1 Pages Shipper's Reference Number (optional)
Consignee Dr Poh Virus Research Lab 20119 Berlin Deutschland Germany	

1. Enter name and address of Shipper and Consignee
2. Enter Air waybill number if you have it. (This information can be filled up by any other person besides the shipper)
3. Enter page of pages (i.e. 1 of 1)



Problem Solution

<i>Two completed and signed copies of this Declaration must be handed to the operator.</i>		WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law , subject to legal penalties.			
TRANSPORT DETAILS					
This shipment is within the limitations prescribed for : 5 (delete non-applicable)		Airport of Departure Singapore 4			
<table border="1"><tr><td>PASSENGER AND CARGO AIRCRAFT</td><td>CARGO AIRCRAFT ONLY</td></tr></table>		PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY		
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY				
Airport of Destination : <u>Berlin, Germany</u> 4		Shipment type : (delete non-applicable) 6 <table border="1"><tr><td>NON-RADIOACTIVE</td><td>RADIOACTIVE</td></tr></table>		NON-RADIOACTIVE	RADIOACTIVE
NON-RADIOACTIVE	RADIOACTIVE				

4. Enter the full name of the airport or city of departure/destination (these details can be filled up by any other person besides the shipper)
5. Delete one on Transportation details: Passenger and Cargo, or Cargo Aircraft Only (in this case, "CARGO AIRCRAFT ONLY" is deleted. Because only both passenger and cargo aircraft are allowed as the total net quantity is 40 ml which does not exceeds max 50ml net quantity per package allowed in passenger aircraft)
6. Delete one on shipment type: Non radio active or Radio active(in this case, "RADIOACTIVE" is deleted)

Problem Solution

Fill up Nature and Quantity of Dangerous Goods:

NATURE AND QUANTITY OF DANGEROUS GOODS (see sub-Section 8.1 of IATA Dangerous Goods Regulations)						
Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID NO.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
UN 2814	Infectious substance, affecting humans (Ebola Virus)	6.2		1 Fiberboard box X 40mL	620	
UN 1845	Dry Ice	9		5kg <u>Overpack used</u>	954	

7

8

9

10

- UN shipping number (the prefix “UN” must be present)
- Proper Shipping Name (for division 6.2, remember to include the name of virus to be shipped)
- Class or Division (Subsidiary Risk) (where applicable)
- Packing Group (Note: There is no packing group for Class 6.2 and dry ice)

Problem Solution

Fill up Nature and Quantity of Dangerous Goods:

NATURE AND QUANTITY OF DANGEROUS GOODS (see sub-Section 8.1 of IATA Dangerous Goods Regulations)						
Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID NO.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack- ing Group			
UN 2814	Infectious substance, affecting humans (Ebola Virus)	6.2		1 Fiberboard box X 40mL	620	
UN 1845	Dry Ice	9		5kg <u>Overpack used</u>	954	

11

12

13

11. Quantity and type of packing

- Net quantity (must include unit of measurement)
- Type of packing, e.g. 1 Fiberboard Box,
 - for dry ice in overpack, state "overpack used"

12. Packing instruction

13. Authorization

- Relevant special provisions are to be entered here (found in DGR section 4)



Today's Problem

Additional Handling Information	
14	
24-hour emergency telephone number : <u>+65 91234567</u> (including country and area code)	
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name , and are classified , packaged , marked and labeled/placarded , and are in all respects in proper condition for transport according to applicable <u>international</u> and national governmental regulations. I declare that <u>all</u> of the applicable air transport requirements have been met.	Name/Title of Signatory Kenny Lim/Operations Executive Place and Date Singapore, 03 Feb 2020 Signature Kenny L. (See warning above)

14. Under additional handling information, add 24 hr. emergency contact details (Telephone number must be preceded with country and district code. Telephone number of guard room is not acceptable)

15. Sign off the form, name, title, place and date. Person responsible should be IATA trained and certified. (Do not use initial and abbreviate, e.g M.C.Donald, A. Director)

Finally, conduct a self check, if possible with the operator's checklist



Learning Outcomes

- Interpret the ICAO/ IATA standards for transportation of pharmaceutical and bio-chemical products and hazardous materials.
- Identify the various relevant sections and know how and where to retrieve critical information contained in the different sections in IATA DGR to do DG declaration.
- Apply ICAO/ IATA guidelines and demonstrate proper declaration for pharmaceutical and bio-chemical products and hazardous materials.

