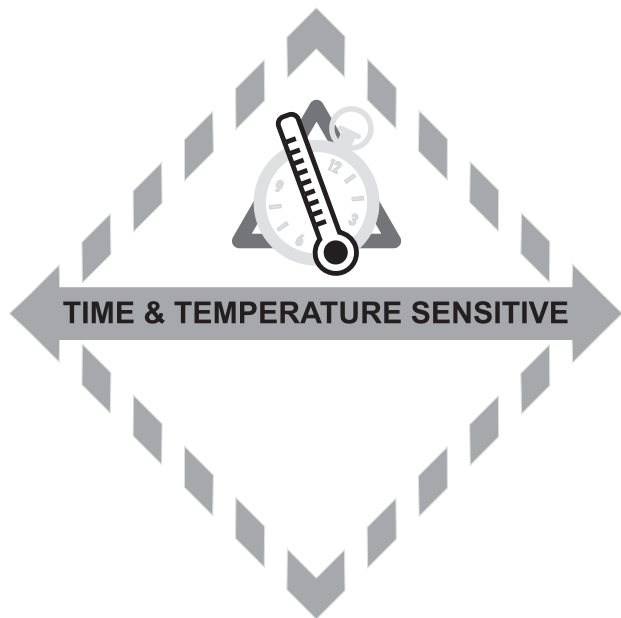


□ 17.10.5 The Label

As of the 10th edition of the Perishable Cargo Regulations manual, effective 1 July 2010, all time and temperature sensitive healthcare product shipments should be labelled with the standard IATA “Time and Temperature Sensitive” label:



- a) Name of Label: Time and Temperature Sensitive for Healthcare Products
- b) Colour: Blue printing on white background
- c) Size: 10cm × 10cm (4 × 4 in)
- d) Variation: the label should be available either in adhesive or “tie-on” format

□ 17.10.6 Instructions for use of the IATA Time and Temperature Sensitive Label

The “Time and Temperature Sensitive” label has been designed to suit the varying needs of shippers, individual airline carriers, and other partners within the logistics cold chain. Unless otherwise specified in a contractual agreement, it is the responsibility of the shipper to apply the Time and Temperature Sensitive Healthcare Product label to the individual shipping packages, overpack or bulk container to be shipped.

The label may also be applied by the carrier, forwarding agent or other third party service provider if agreed to by the shipper in a Quality Management Systems document or approved SOP. The label must be affixed to at least 1 side panel of each individual package. Where appropriate, packages of healthcare products should also be

labelled with the standard IATA package orientation (THIS WAY UP) label.

Note:

Dry-ice when used as a refrigerant; dry-ice is classified as “dangerous goods” and it is therefore necessary to refer to the IATA Dangerous Good Regulations for details of additional labelling and marking requirements.

1. When specific arrangements have been agreed to between the shipper and the carrier with respect to acceptable information to be shown on the label(s):
 - (a) The lower blank triangle of the label must be used to indicate the allowable temperature range or limit that the package can be exposed to during transportation and distribution. The lower blank triangle of the label may also be used to communicate SOP's or other non-temperature handling information. Under these circumstances, the Time and Temperature Sensitive label overrides all other handling labels which may be on the package.
 - (b) When there are no specific agreements for the temperature range or additional handling requirements indicated, the lower triangle of the label should be left blank. It is assumed that every effort will be made to maintain the package within a range of +15°C to +30°C during transportation, wait times, and distribution.
 - (c) In all cases, the Celsius scale and English language must be used.
 - (d) The handling and storage temperature indicated on the label must correspond to the handling & storage temperature indicated by the shipper on the shipping or handling instructions, Air Waybill/House Air Waybill or Standard Operating Procedure (SOP) that have been agreed with the forwarder, handling company, individual airline carrier or other partners within the logistics cold chain.
 - (e) Suitable temperature ranges, or indications, may include but are not limited to:
 1. +2°C to +8°C
 2. +2°C to +15°C
 3. +2°C to +25°C
 4. +15°C to +25°C
 5. Keep frozen
 6. Do not freeze

17.10.7 Specific Instructions for Active Temperature-Controlled Containers:

1. The Time and Temperature Sensitive label format and logo may be incorporated into the IATA ULD label or tag already in use by carriers.
2. The lower (blank) triangle on the label may be used to indicate specific storage requirements of an active container.

17.11 Training Programs

Referring to the Quality Management System section of this chapter, personnel must be trained to perform their assigned functions. Training should address the policies, processes, procedures, and written instructions related to operational activities, the product/service and the quality system. There should be initial, on-going training as well as periodic assessments of previous training.

Management should also define those positions that require training and the content should be relevant to the individual's responsibilities and scope of work. It is also necessary to define both the periodic training requirements and frequency of training.

Material for the training program can be obtained from such sources as the packaging provider, the supplier's processes and procedures, airline manuals, industry guidance (such as Technical Report #39 and USP Chapter 1079) and state regulatory documents.

While training can be conducted using a variety of methods, any computer or classroom based training should be supplemented with a practical "hands on" session to reinforce the learning. The training should include an assessment; either in the form of a written test or by having individuals demonstrate their ability to perform certain tasks. A record of the training should be documented within the individual's personal records.

In some cases, training may be limited to having personnel read through and "sign off" that they have reviewed and understand defined procedures. However, without further training, this method is not recommended for those who are responsible to make decisions that are beyond the scope of the procedures.

The following is a recommended training and competency matrix. The training program could be part of broader scope training that includes other perishable products.

Table 17.11A

| Training Topic (as applicable) | Quality / Senior Manager Department /Section Manager | Product Manager / Sales Manager | Training Manager | Customer Service & Ordering | Technical Support | Personnel loading product | Warehouse Personnel | Ramp Personnel | Ground Transportation | Import Agent / Broker | Personnel handling DG |
|---|--|------------------------------------|------------------|-----------------------------|-------------------|---------------------------|---------------------|----------------|-----------------------|-----------------------|-----------------------|
| GENERAL | | | | | | | | | | | |
| Pharmaceutical industry overview | ✓ | ✓ | ✓ | | | | | | | | |
| IATA Perishable Cargo Manual Chapter 17 | ✓ | ✓ | ✓ | | | | | | | | |
| Effects of temperature on pharmaceuticals | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ |
| Passive and active packaging | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | |
| Quality policy / procedures | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ |
| Company product service offering | ✓ | ✓ | ✓ | ✓ | ✓ | | | | | | |
| Job responsibility, authority & reporting | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| TRAINING | | | | | | | | | | | |
| Training program / reporting / review | ✓ | ✓ | ✓ | ✓ | | | | | | | |
| DG handling / acceptance procedures | | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| PROCEDURES & CHANGE CONTROL | | | | | | | | | | | |
| Documentation, marking, labelling | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Storage, warehouse and ramp handling | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Aircraft and truck transport | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Procedures related to job function | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Document & process change control | ✓ | ✓ | ✓ | | | | | | | | |
| Equipment/facilities requirements & maintenance | | ✓ | | | | | ✓ | ✓ | ✓ | ✓ | ✓ |
| CORRECTIVE & PREVENTIVE ACTION | | | | | | | | | | | |
| Contingency planning & escalation process | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Investigation & reporting process | ✓ | ✓ | | | | | | | | | |
| SPECIFIC TO ACTIVE ULD PLATFORMS | | | | | | | | | | | |
| Active ULD specifications | | | ✓ | ✓ | ✓ | | | | | | |
| Ambient limits / handling | | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | |
| Contingency planning | | | ✓ | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | |

17

17.11