



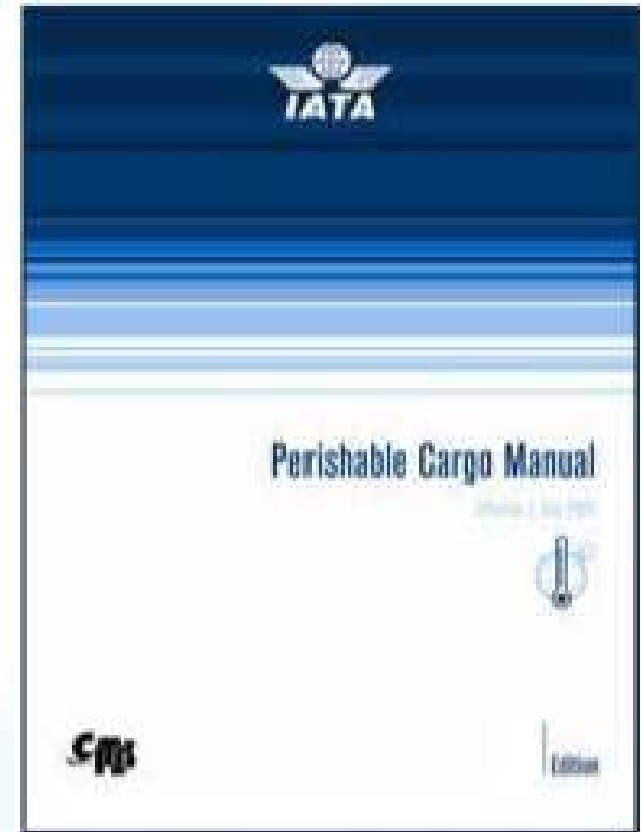
**CNS Partnership Conference
Time & Temperature Track**

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Implementing IATA Ch. 17: Rules to Reality

- ▶ Delicate balance between:
 - interests of the healthcare industry faced with increasing regulatory measures for global distribution of temperature sensitive healthcare products
 - airlines struggling to maintain profitable growth in a difficult market environment where profit margins are decreasing and cost saving a means of survival.
- ▶ How are the guidelines of IATA ch. 17 being “lived” in the “real world”?



Managing cold chain service providers





- ▶ Pharmaceutical companies are focusing not only on GMP, but more and more also on GDPs to ensure that the product arrives up to the patient in good condition
- ▶ Quality risk assessments done of transportation service providers to determine level & frequency of performance management including:
 - Questionnaires/Vendor form
 - On-site audits
 - Contractual agreements (SLA, TA, etc.)
 - SOPs
 - Review Meetings
- ▶ Supply chain partners include airlines, freight forwarders, 3PL/4PL, etc.

40+ airports assessed worldwide



LifeTrack
Database

  Airports we work with (2009)
Stations assessed as of April 2010

Airport assessment guidelines & checklists

Objectives:

- ▶ to evaluate the services, specific processes and facilities required for the transport of temperature sensitive goods
- ▶ to check compliance with the written information provided by the carrier in the LifeConEx internal knowledge data base
- ▶ to identify areas for improvement, initiate corrective actions and check results of corrective measures

	Carrier Station Ev	
	<i>DOCUMENT:</i>	5 1.10 Carrier Station Evaluation

#	Type	Topic	Y/N	Activity
46	Service	Coolcontainers		Does airline offer Coolcontainer service at the airport?
47	Service	Coolcontainers		Re-icing procedure?
48	Service	Coolcontainers		Battery procedure?
54	Service	Tarmac		What is the time between the moment the goods leave the warehouse and the moment the goods are loaded into the aircraft (time goods are exposed on the tarmac)?
55	Service	Tarmac		Who manages the transportation from the warehouse to the tarmac? Who is the loading agent?
56	Service	Aircraft hold		Are special instructions provided to the captain for temperature

Examples of elements included

- ▶ Warehouse: cool room facilities (capacity, temperature set, calibration, alarms, etc.), housekeeping & security
- ▶ Staff : subcontracted ground handlers, employee training
- ▶ Working procedures for handling temperature-sensitive healthcare products
- ▶ Exception management: shipment monitoring, communication
- ▶ Airport infrastructure and tarmac transportation
- ▶ Local government customs & healthcare authorities
- ▶ And more ...

Airline service offers for temperature sensitive life sciences shipments



- ▶ Competence centers in strategic locations managing all “special” cargo & located at the central hub
 - Coordination of both internal and external communication 24/7
 - “Experts” handling irregularities (real-time and post-shipment) and ensuring SOP compliance (incl. local responsible persons)
- ▶ Standard procedures & trained staff
- ▶ Defined storage conditions on the ground (i.e. limited tarmac time, limited exposures to ambient conditions, cool room facilities)
- ▶ Required storage temperatures in-flight (i.e. Notoc)
- ▶ Additional service for active container
 - Container leasing directly through the airline
 - Procedures and trained staff to provide container handling including proper handling, dry ice replenishment and battery replacement/charging (as required)
 - Regular temperature and voltage checks (i.e. container check sheet)

Challenges faced by the airlines

- ▶ Local government/airport restrictions
- ▶ Limited infrastructure
- ▶ Cost pressure
- ▶ Numerous subcontracted ground handlers
- ▶ Low volume/high value shipments
- ▶ Confusing instructions
- ▶ High complexity
- ▶ Demand for product segregation



So what is the reality?

- ▶ Deep frozen and +2 to +8°C cool rooms are becoming quite common yet standards vary greatly
- ▶ +15 to +25°C are extremely rare yet the expectation is that this will be more and more of a focus by the regulatory bodies in the coming years
- ▶ Need for training and more training – at operational working level!
- ▶ In-flight cargo hold temperatures are still a big unknown
- ▶ The number of audits is increasing – can centralized auditing based on ch. 17 be coordinated through IATA?

Lessons learned

- ▶ Regular customer audits due to requirement from health authorities to demonstrate subcontractor management
- ▶ Better understanding of the reality vs. paper as well as the challenges faced by many airlines
- ▶ Experience gained very valuable in evaluating key risk factors and how to best manage these
- ▶ Don't believe the hype as only seeing is believing!
- ▶ Major hubs airports do not always meet expectations while others have been pleasant surprises (no assumptions!)
- ▶ Even the best on-site assessment and SOP is only as good as the reality of each individual shipment.

Quality assurance with airlines & ground handlers



- ▶ Verify SOP compliance at each touch point (phone, email or provider system information)
- ▶ Report all agreed-upon metrics with accurate records
 - Real-time data wherever possible
 - Storage locations and conditions
 - Active container temperature readings
 - All process deviations and potential threats to the product
- ▶ Timely intervention when required to protect the product
- ▶ Post shipment management of process deviations (internal & external)
- ▶ Regular performance reviews among all parties

**Thank you for your
attention!**

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