Leading Minds Seminar

IATA Dangerous Goods Regulations Implementation in the Pharmaceutical Supply Chain

Who is IATA?

- The trade association for the world's airlines, representing 84% of global air traffic
  - Currently 274 member airlines (April 2017)
- Founded in 1945 in Havana, Cuba by 30 airlines
- Incorporated in Canada by a special Act of Parliament
- IATA's mission is to represent, lead and serve the airline industry

Meet the team

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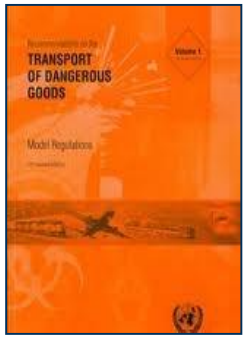
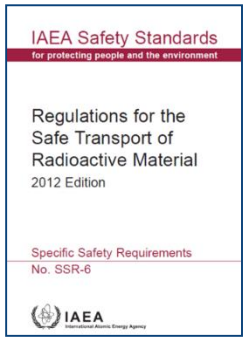
Basis of The Regulations

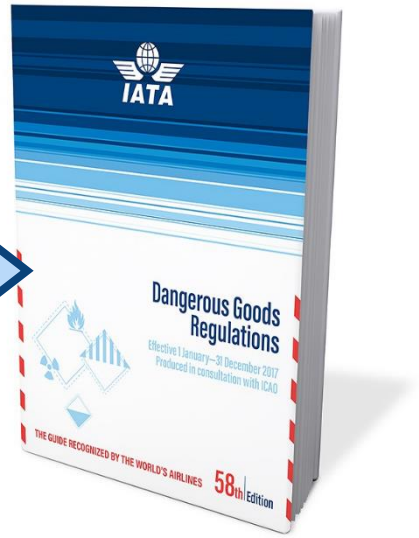
UN Subcommittee of Experts on the Transport of Dangerous Goods (SCoETDG) / Orange Book



International Atomic Energy Agency SSR-6



ICAO Technical Instructions



IATA's Dangerous Goods Activities

- The first edition of the IATA *Dangerous Goods Regulations* was published in 1956 as the IATA Restricted Articles Regulations
- Developed by the IATA Dangerous Good Board – composed of 12 member airlines
- Voting member at the ICAO Dangerous Goods Panel
- Participate at the UN Sub-Committee of Experts
- Participate at IAEA meetings

IATA's Dangerous Goods Regulations

- Incorporates all of the legal requirements of the ICAO TI
- The recognized "field manual" for shipping dangerous goods by air
- Published in 5 languages
- There are certain differences between the IATA and ICAO regulations which stem from operational considerations ☞
- The "Dangerous Goods Regulations" are binding upon IATA member airlines in scheduled and unscheduled operations

State and Operator Variations

- State Variations:
  - apply to, from or through all territory subject to the sovereignty of the notifying State (country) by all operators;
  - outside the territory of the notifying State to its operators (airlines).

- Operator Variations:
  - **can only be more restrictive** ☞
  - apply to the notifying operator wherever it is operating

State and Operator Variations

- Examples of Operator Variations:
- QR (Qatar Airways)

QR-04 The following will not be accepted for carriage on Qatar Airways passenger flights:

- UN 3091—lithium metal batteries contained in equipment;
- UN 3091—lithium metal batteries packed with equipment.

The above include both Section I (fully regulated) and Section II (excepted) **(see PI 969–970)**.

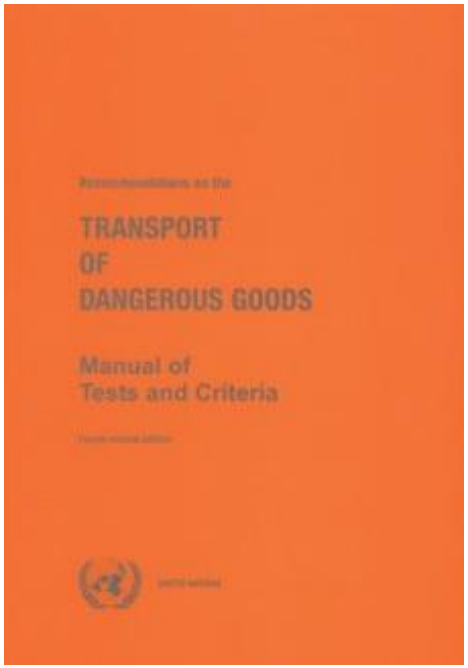
- ☐ Lithium battery powered temperature loggers for pharmaceutical shipments are permitted with prior approval from email: qrdg@qatarairways.com.qa

Current Regulatory Requirements

UN Manual of Tests and Criteria - 38.3 tests

- T1 – Altitude simulation
- T2 – Thermal
- T3 – Vibration
- T4 – Shock
- T5 – External short circuit
- T6 – Crush
- T7 – Overcharge
- T8 – Forced discharge

Exceptions for prototype & low production (<100) batteries (SP A88)




Signature Required

Packing Instructions

- Six different packing instructions apply:
  - Lithium ion batteries (965)
  - Lithium ion batteries packed with equipment (966)
  - **Lithium ion batteries contained in equipment (967)**
  - Lithium metal batteries (968)
  - Lithium metal batteries packed with equipment (969)
  - **Lithium metal batteries contained in equipment (970)**
- Each Packing Instruction details requirements for fully regulated and for excepted packages (shown in Section II).

Lithium ion cells/batteries – Contained in equipment, UN3481 (PI967)

Section I

Per cell > 20 Wh
Per battery > 100 Wh

Per package 5/35 kg

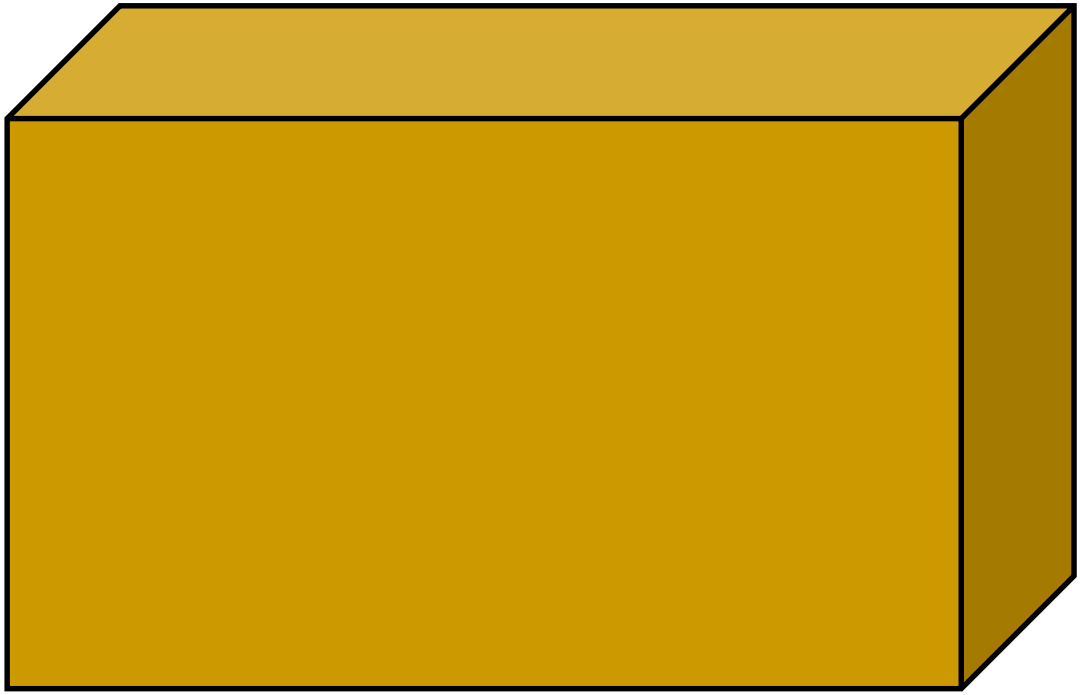
Section II

Per cell <= 20 Wh
Per battery <= 100 Wh

Per package 5/5 kg

If more than 4 cells or 2 batteries

Lithium ion batteries contained in equipment, Packing Instruction 967 section II



Not more than 4 cells or 2 batteries

Lithium ion batteries contained in equipment, Packing Instruction 967 section II

More than 4 cells
or 2 batteries

Lithium metal cells/batteries – Contained in equipment, UN3091 (PI970)

Section I

Per cell > 1g
Per battery > 2g

Per package 5/35 kg

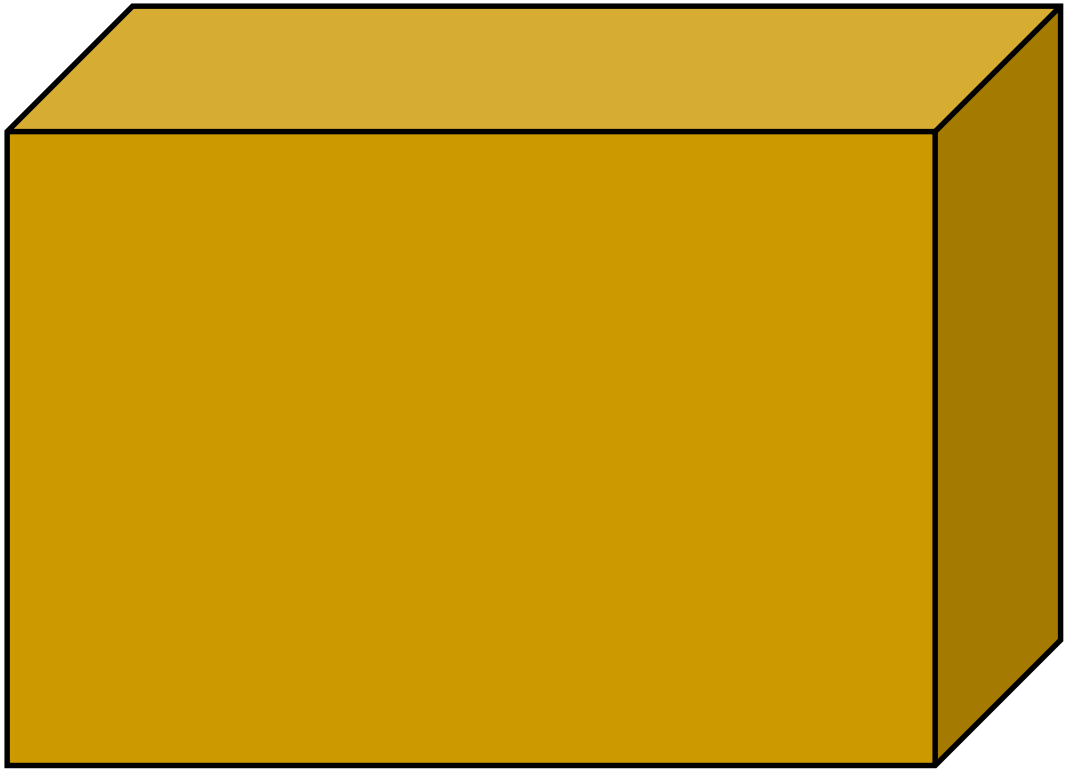
Section II

Per cell <= 1g
Per battery <= 2g

Per package 5/5 kg

If more than 4 cells or 2 batteries

Lithium metal batteries contained in equipment, Packing Instruction 970 section II



Not more than 4 cells or 2 batteries

Lithium metal batteries contained in equipment, Packing Instruction 970 section II

More than 4 cells
or 2 batteries

59th Edition DGR Changes - Summary

- IATA DGB:
  - develop changes to 2018 DGR to address safety & operational issues
- Appendix I – Impending changes:
  - UN alignment revisions
  - Changes adopted by ICAO DGP as known
  - competency-based dangerous goods training

IATA DGR Changes

- **Subsection 2.3 – DG Permitted by Passengers**
  - Restriction on the number of PED that a passenger can have (15) and the number of spare batteries (20).
    This can be exceeded with the approval of the operator.

IATA DGR Changes

- **Section 5 – Packing**
  - 5.0.1.5.1 – prohibition on placing packages of lithium batteries (UN 3090 & UN 3480) in an overpack with packages containing dangerous goods in Class 1, except 1.4S, Div. 2.1, Class3, Div. 4.1 and Div. 5.1.
  - 5.0.2.11 – prohibition on packing lithium batteries (UN 3090 & UN 3480) in same outer packaging with dangerous goods in Class 1, except 1.4S, Div. 2.1, Class3, Div. 4.1 and Div. 5.1.

IATA DGR Changes

- **Packing Instructions**
  - PI 965 & PI 968 – text has been added to address restrictions on packing or overpacking lithium batteries with flammable dangerous goods. For Section II packages must not contain any other dangerous goods.

IATA DGR Changes

- **Section 7 – Marking and Labelling**
  - 7.1.5.5.2 – text has been added recommending that the UN number(s) on the lithium battery mark be a minimum size.

IATA DGR Changes

- **Section 9 – Handling**
  - 9.3.2 and Table 9.3.A – have been revised to require segregation between packages and overpacks containing lithium batteries (UN 3090 & UN 3480) and packages and overpacks containing dangerous goods in Class 1, except 1.4S, Div. 2.1, Class3, Div. 4.1 and Div. 5.1 when loaded into a ULD or cargo compartment.

Recommendation for 2018, mandatory from 2019.

Appendix I – Impending Changes

Classification

- Provision for hybrid lithium batteries that contain both lithium metal cells and lithium ion cells not designed to be externally recharged.

- Requirement for manufacturers and subsequent distributors of cells or batteries to make available the test summary as specified in the UN *Manual of Tests and Criteria*.

Lithium cell or battery test summary in accordance with sub-section 38.3 of Manual of Tests and Criteria

The following information shall be provided in this test summary:

(a) Name of cell, battery, or product manufacturer, as applicable;
(b) Cell, battery, or product manufacturer's contact information to include address, phone number, email address and website for more information;
(c) Name of the test laboratory to include address, phone number, email address and website for more information;
(d) A unique test report identification number;
(e) Date of test report;
(f) Description of cell or battery to include at a minimum:
  (i) Lithium ion or lithium metal cell or battery;
  (ii) Mass;
  (iii) Watt-hour rating, or lithium content;
  (iv) Physical description of the cell/battery; and
  (v) Model numbers.
(g) List of tests conducted and results (i.e., pass/fail);
(h) Reference to assembled battery testing requirements, if applicable (i.e., 38.3.3 (f) and 38.3.3 (g));
(i) Reference to the revised edition of the Manual of Tests and Criteria used and to amendments thereto, if any; and
(j) Signature with name and title of signatory as an indication of the validity of information provided.

Dangerous Goods List

- New UN Numbers:
  - UN 3535 Toxic solid, flammable, inorganic, n.o.s., 6.1 (4.1)
  - UN 3536 **Lithium batteries installed in cargo transport unit**, 9
  - UN 3537 Articles containing flammable gas, n.o.s., 2.1
    to
    UN 3548 Articles containing miscellaneous dangerous goods, n.o.s., 9
    Does not apply to Class 1, Division 6.2 or Class 7

Section 7 – Marking & Labelling

- The 2 mm line has been removed!

UN Subcommittee of Experts

- Proposal to except data loggers and cargo tracking devices from the regulations.
  - Text provisionally adopted into UN Model Regulations that would except data loggers / tracking devices containing lithium batteries attached to CTU, packages or overpacks.
  - Intersessional working group to consider.
- Working group established to develop a hazard-based approach to the classification of lithium batteries.

UN Subcommittee of Experts

Chapter 1.1

[1.1.1.2 Amend paragraph (c) to read as follows:

"(c) Lithium battery powered cargo tracking devices or data loggers attached to packages, overpacks or cargo transport units if they meet the following:

(i) Each cell or battery meets the applicable provisions of 2.9.4;

(ii) The batteries and cells are afforded protection by an outer casing of adequate strength and design or by the device in which they are contained to prevent damage under normal conditions of transport.".]

(Reference document: ST/SG/AC.10/C.3/2017/13, as amended)

Final meeting for next UN Model regulations Dec 2018, therefore the earliest introduction to the ICAO TI would be 1 Jan 2021

UN Subcommittee – The Future

Possible categorization of lithium batteries for transport according to their hazards and effects when reacting

There is discussion about assessing the effects of batteries reacting in an accident and their intensity with the goal of proposing a categorization of lithium batteries according to their behavior when reacting more or less violently.

The idea of creating such a classification comes most notably from the great variety of battery types being transported in terms of their geometry, chemical composition and design, which leads to varying behavior when batteries are subjected to accidental situations,

UN Subcommittee – The Future

5 Most common cathode materials

- Cobalt oxide – High energy density, low auto-discharge, high cost, low thermal stability
- Nickel-manganese-cobalt oxide – higher thermal stability, lower cost
- Nickel-cobalt-aluminium oxide – high energy density, long stability over time
- Manganese oxide – long term cycleability, lower cost
- Iron phosphate – strong thermal stability, low energy density

2 Most common anode materials

- Graphite
- Lithium titanate

Considerations for dry ice shipments in air cargo

- US DoT Advisory Circular 2009 recommended shippers use a 2% sublimation rate for packages

$$X = \text{Dry ice loading in lb}$$

$$X = \frac{(CO_2 \text{ concentration})\ (\text{Aircraft Volume, } ft^3)\ (\text{Complete air exchanges per hour*})}{(\text{sublimation rate})}$$

G27 Packaging standard

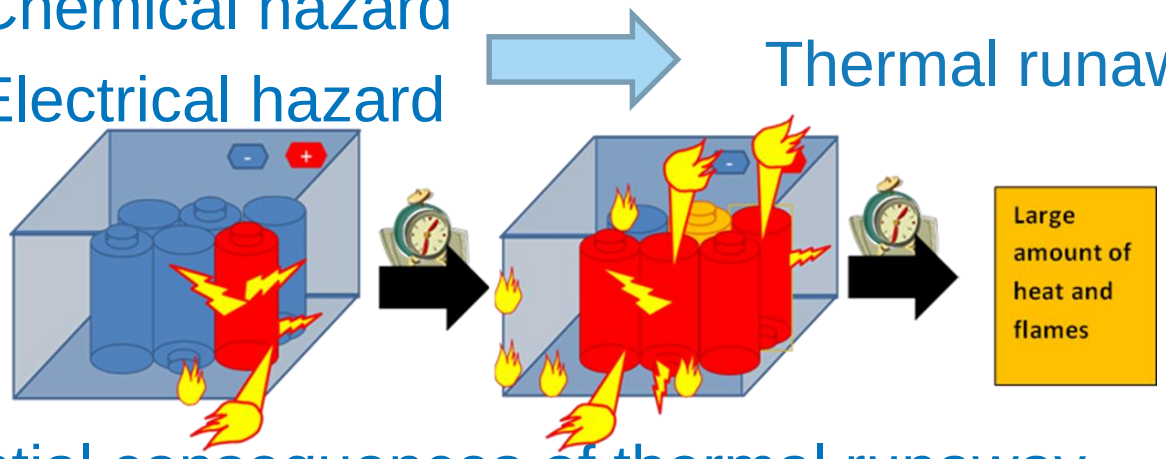
- ICAO determined that containment is required at package level
- SAE was mandated for developing the standard
- G-27 is the SAE committee for the “lithium battery packaging performance standard”
- A multi-layered risk mitigation approach must be considered:
  - Cell/battery - packaging - ULD - cargo hold - aircraft
- Multiple controls can be applied at each stage

Why do we need a packaging standard for Lithium Batteries?

- Lithium batteries have potential for self ignition
- There is a risk of reaction propagation
- Aircraft fire suppression systems may be incapable of extinguishing some battery fires
- Lithium battery volumes carried by air are increasing due to increased consumer demand
- Previous fire incidents where lithium batteries are involved – possible root cause?

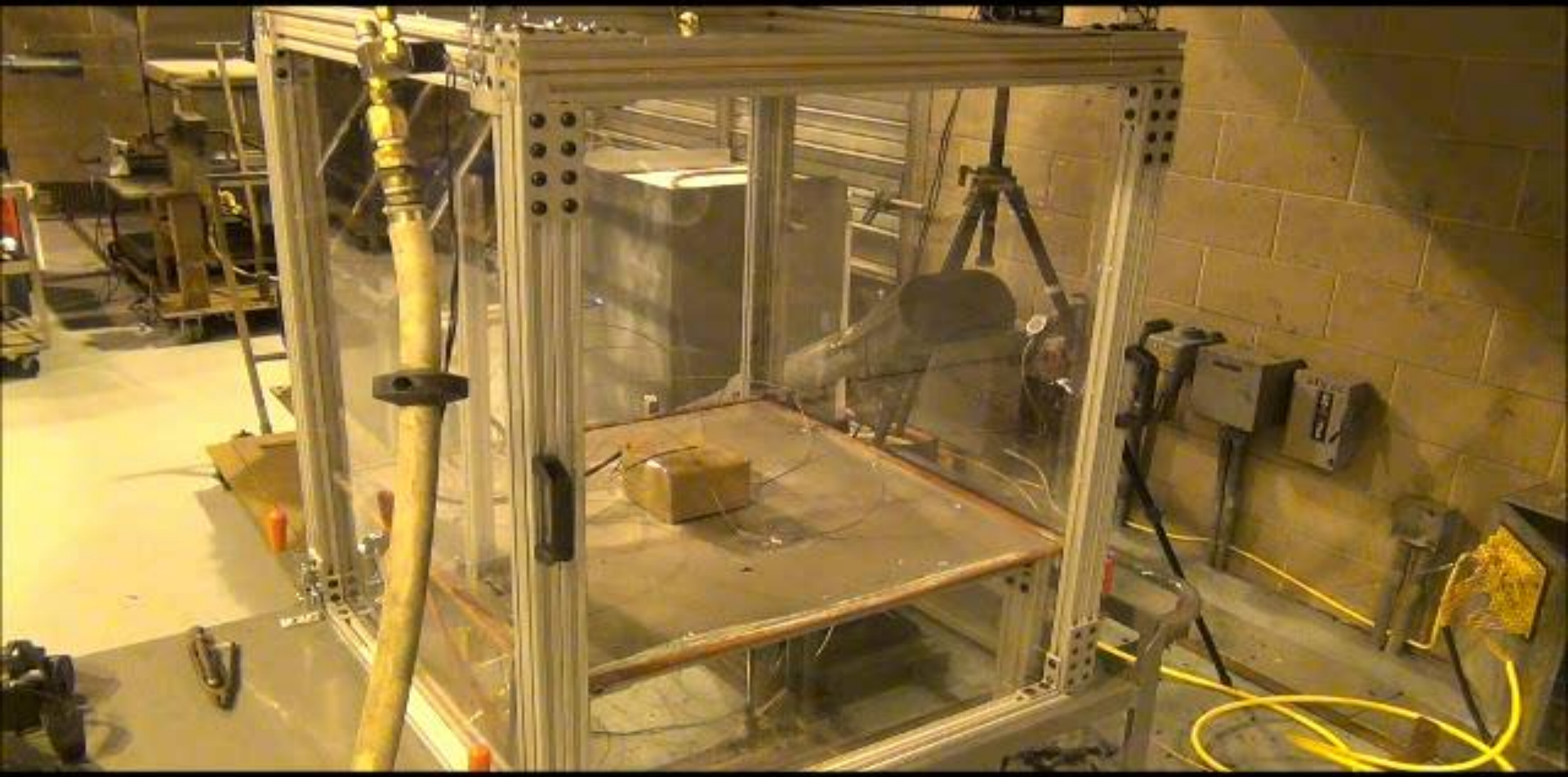
What hazards need to be controlled?

- The Chemical hazard
- The Electrical hazard



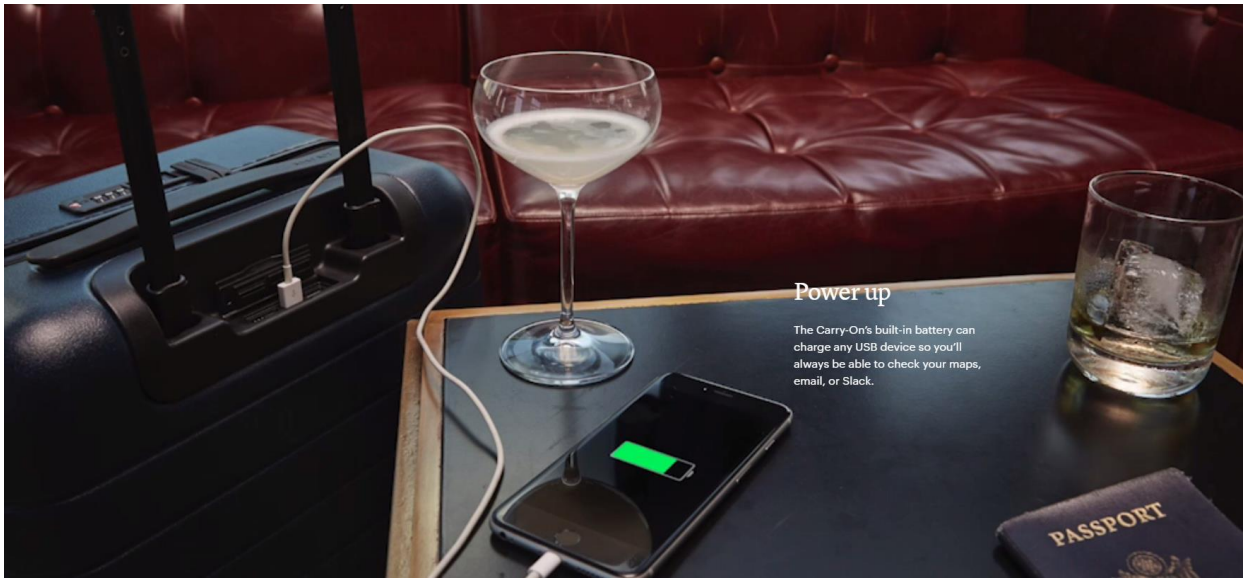
- Potential consequences of thermal runaway
  - Flammable/toxic gas emission (possibly bursting)
  - Flame ignition, and possible flame propagation in the cells or batteries casing/packaging.
  - Heat emission and Thermal Runaway Propagation from cell to cell or battery to battery, in absence of flames

Lithium Metal Class C Video



The evolution of regulations

- Speed of technological innovation outpaces regulatory change



IATA's Future Developments

- Automation of the DG Acceptance Check Process
- Tablet based tool - Shipper's Declarations can be uploaded in electronic form or can be scanned from paper.
- DG AutoCheck will check the Shipper's Declaration against the DGR.
- It will show the checker the required labels and markings for visual inspection of the package
- DG AutoCheck provides management oversight of all DG checks and an interface to your training database

Questions?

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