DGP/29-IP/9
11/11/23

# DANGEROUS GOODS PANEL (DGP)

## TWENTY-NINTH MEETING

**Montréal, 13 to 17 November 2023**

**Agenda Item 4: Managing safety risks posed by the carriage of lithium batteries by air *(Ref: Job Card DGP.003.04)***

## REPORT OF THE FACE-TO-FACE MEETINGS OF THE DANGEROUS GOODS WORKING GROUP ON ENERGY STORAGE DEVICES CONVENED ON 9 AND 10 NOVEMBER 2023 AND ON 14 NOVEMBER 2023

(Presented by the Rapporteur of DGP-WG/Energy Storage Devices)

**SUMMARY**

DGP-WG/Electronic Storage Devices met on 9 and 10 November 2023 and on 14 November 2023 to review the results of its analysis on the transport of lithium batteries packed with and contained in equipment presented in DGP/29-WP/41 and to develop recommendations for DGP/29. The report of the meeting from 9 and 10 November 2023 is provided in paragraph 1 of this information paper and the report of the meeting on 14 November is provided in paragraph 2 of this information paper.

## 1. REPORT OF 9 TO 10 NOVEMBER 2023

1.1 The DGP-WG/Electronic Storage Devices met from 9 to 10 November 2023 to review the proposals to apply a reduced state of charge to lithium ion batteries packed with and contained in equipment presented in DGP/29-WP/6, the results of the analysis presented in DGP/29-WP/41 and to develop recommendations for DGP/29. Over the course of two days the working group:

a) Reviewed DGP/29-WP/41 and associated information papers DGP-IP/2 and DGP-IP/3;

b) Received an update on lithium battery and devices air transport incident data reported through the voluntary Thermal Runaway Incident Program (TRIP) (see Appendix A);

c) Reviewed data related to U.S. Import-Export Data on UN 3480/UN 3481/UN 3090 (Appendix B);

d) Reviewed a letter identifying implications of potential state of charge on limit on medical devices (Appendix C); and

e) Reviewed comments from DGP/28 (Appendix D).

1.2 The working group considered whether risks associated with the air transport of lithium ion batteries packed with equipment and lithium ion batteries contained in equipment are adequately mitigated in light of all of the available information. Starting with lithium ion batteries packed with equipment, Section I, the group recognized that there are no limits on the size of such batteries and concluded risk is currently not adequately mitigated and a state of charge limit is warranted. For lithium ion batteries packed with equipment, Section II, the group recognized that this encompasses a range of battery sizes from the very small batteries that pose a negligible hazard up to batteries of 100 Wh that pose a greater hazard. The group recognized the need to apply safety requirements proportionate to the hazard and a single requirement across this range of products in this case may be excessive. Based on experience and testing on smaller cells and batteries up to 2.7 Wh, the group concluded that these very small cells and batteries did not pose an unacceptable risk but those greater than 2.7 Wh did.

1.3 The working group agreed to amend PI966, Section I to require cells and batteries to be shipped at a state of charge not exceeding 30% of the rated capacity. A mechanism to approve cells and batteries packed with equipment to be shipped at higher states of charge would be provided. The working group also agreed to amend PI966 Section II to require lithium ion batteries packed with equipment exceeding 2.7 Wh to be shipped at a state of charge not exceeding 30 per cent. The group also agreed that approval provisions should be added to allow shipments of lithium ion batteries packed with equipment to be shipped at higher states of charge.

1.4 The group then considered whether it was appropriate to apply similar controls to lithium ion batteries contained in equipment. There was some support for requiring a state of charge limit for batteries contained in equipment, but the majority could only support a recommendation. All agreed there was a safety risk that needed to be mitigated, but those not in support of a requirement did not consider the risk high enough to warrant a requirement that would significantly impact industry, particularly with respect to the shipment of medical devices some of which are required to remain in sterile packaging and must be ready to use upon receipt, large information technology equipment with embedded lithium ion batteries and military equipment. They considered batteries packed with equipment to pose a similar risk as batteries packed with their own, while batteries contained in equipment posed a lesser risk because of the protection the equipment provided and lesser energy densities. They did not consider the TRIP data presented to be relevant or sufficient to justify a requirement. They believed that the incidents were largely due to non-compliant shipments. Those who supported a requirement based their support on the outcome of the STPA and a consideration of arguments presented at DGP/28. They believed the TRIP data was relevant and that waiting for more data was a reactive approach.

1.5 The group also considered reducing Section II quantity limits for cells and batteries packed with equipment. The Technical Instructions in Packing Instruction 966, Section I permit up to 5 kg of lithium ion cells or batteries per package on passenger aircraft and up to 35 kg of lithium ion cells or batteries per package on cargo only aircraft. Packing instruction 966, Section II permits up to 5 kg of lithium ion cells or batteries per package on passenger aircraft and cargo only aircraft. Additionally, the packing instruction permits up to the maximum number of cells or batteries required to power the

equipment plus two spare sets. Reductions in package quantity limits were discussed as a potential way to reduce the amount of cells or batteries contained in a package.

1.6 The group reviewed DGP/29-IP/2 that included a list of potential additional requirements scored against the mitigation order of precedence. The group identified additional scenarios and recommendations to that previously indicated in DGP/29-IP/2. The group identified a new causal scenario CS.1.1A for invalid lithium battery test reports and an additional mitigation measure to CS 2.1, 3.1, 3.2 and 4.1. This mitigation measure would add a requirement for packages to be capable of withstanding a 3-meter stack test similar to that required for packages containing limited quantities. The group determined that some of the other items are outside of the scope of the DGP or otherwise were not feasible while others could be considered for future action. The results of this review are provided in the Appendix E.

## 2. RECOMMENDATIONS: 9 TO 10 NOVEMBER 2023

2.1 DGP-WG/Electronic Storage Devices formulated the following recommendations with respect to incorporating a state of charge limit for lithium ion batteries packed with and contained in equipment following a review of the results its analysis on the transport of lithium batteries packed with and contained in equipment:

a) require that UN 3481 — **Lithium ion batteries packed with equipment** with a Watt hour rating greater than 2.7 Wh to be offered for transport at a state of charge not exceeding 30 per cent of their rated capacity[1];

b) allow cells and/or batteries packed with equipment to be shipped at a state of charge greater than 30 per cent of their rated capacity[1] through an approval process;

*Note 1.— Such batteries would be subject to full regulation in accordance with Section I of Packing Instructions 967, and to any other conditions outlined in the approval, even if they are within the limits established to allow exceptions from full regulation in accordance with Section II of Packing Instruction 967.*

*Note 2— DGP-WG/Electronic Storage Devices did not reach a conclusion on who should be involved in the approval process during this two-day meeting. One opinion was that it should be an approval from the States concerned. Another was that it should be an approval of the operator, given they were already responsible for items in their cargo compartment in accordance with Chapter 15 to Annex 6 —* Operation of Aircraft, *Part I —* International Commercial Air Transport — Aeroplanes *and Chapter 12 to Annex 6, Part III —* International Operations — Helicopters. *Most supported having State authorities involved, i.e. the State of Origin and State of the Operator, which was consistent with the provision for an approval to ship UN 3480 at a higher state of charge.*

c) recommend that UN 3481 — **Lithium ion batteries contained in equipment** be offered for transport at a state of charge not exceeding 30 per cent of their rated capacity[1]; and

[1] "a state of charge not exceeding 30 per cent of their rated capacity" may be difficult to achieve by anyone other than the original manufacturer. DGP-WG/Electronic Storage Devices therefore proposes that consideration be given to wording such as meter reading that would make the requirement more practical to implement.

d) add a requirement to packing instructions 966, 967, 969, and 970 that each package must be capable of withstanding, without damage to the equipment contained therein and without any reduction of effectiveness, a force applied to the top surface equivalent to the total weight of identical packages stacked to a height of 3 m (including the test sample) for a duration of 24 hours.

## 3. REPORT: 14 NOVEMBER 2023

### 3.1 Packed with Equipment — Packing Instruction 966:

3.1.1 The group agreed to require lithium ion cells and batteries in excess of 2.7 Wh when packed with equipment to be offered for transport at not more than 30% state of charge limit. An approval provision would be provided in instances in which such batteries must be offered at higher states of charge. The DGP-WG/Electronic Storage Devices initially did not reach a conclusion on who should be involved in the approval process. One opinion was that it should be an approval from the States of origin and operator. Another view was that it should be an approval of the operator, given they were already responsible for items in their cargo compartment in accordance with Chapter 15 to Annex 6 — *Operation of Aircraft*, Part I — *International Commercial Air Transport — Aeroplanes*. Others raised concerns that a state of charge requirement would introduce increased approval burdens.

3.1.2 Eventually, most supported having State authorities involved, i.e. the State of Origin and State of the Operator, which was consistent with the provision for an approval to ship UN 3480 in Packing Instruction 965 to offer lithium ion cells and batteries at a higher state of charge. The group acknowledged that lithium ion batteries packed with equipment are similar to packaged lithium batteries. Deviations from the established approval process for shipping lithium ion batteries UN3480 at higher states of charge in Packing Instruction 965 and prototype and low production batteries in Special Provision A88 would have to have strong justification. The group agreed that no matter how the approval requirement is applied, guidance to assist States with approvals is needed. A framework for this guidance would be most useful prior to presenting to the ANC in February 2024.

3.1.3 The working group will recommend a requirement for lithium ion cells and batteries that exceed 2.7 Wh to be shipped at a state of charge not exceeding 30%. Lithium ion cells and batteries shipped at greater than 30% State of charge will be fully regulated, i.e. packaged, marked and labeled in accordance with packing instruction 966, Section I and approval from the State of origin and the State of operator is required.

### 3.2 Contained in Equipment— Packing Instruction 967

3.2.1 The working group recommended that UN 3481 — Lithium ion batteries contained in equipment be offered for transport at a state of charge not exceeding 30 per cent of their rated capacity. While some felt that a recommendation did not go far enough and had no means of enforcement. Others indicated that a recommendation while only an incremental step could impact operator safety risk assessments and provide an indication that shipments are expected to be offered for transport at a reduced state of charge. Those who did not favor a requirement for a state of charge limit indicated that batteries contained in equipment pose a relatively lower transport risk due to the presence of equipment and certain items of equipment do not have charge indicators making it impossible to comply with a charge limit. A working group members indicated that any amendments applied in the Technical Instructions applicable to civil aviation must also be applied to mail. Doing otherwise would create an uneven system. As the state of charge for lithium ion batteries contained in equipment is a recommendation, this could be

communicated to the appropriate officials at the Universal Postal Union and disseminated through to appropriate postal operators.

3.3 **Draft amendments**

3.3.1 The working group review draft amendments to packing instructions 966 and 967 with respect to a state of charge and packing instructions 966, 967, 969 and 970 with respect to a stack test requirement. The proposal contained a requirement for lithium ion cells and batteries to be offered for transport at a state of charge [as low as practicable, but] not exceeding 30 per cent of their rated capacity. Most sympathized with the intent of the proposal but did not agree that such language is appropriate for regulatory text. It was agreed to create a note indicating that cells and batteries at reduced states of charge pose a lesser hazard when compared to undischarged cells. The optimal state of charge for safety may vary and could be lower than 30%.

3.3.2 The group reviewed proposals for the recommendation for a reduced state of charge for lithium ion batteries contained in equipment. Two choices were presented.

1) Lithium ion cells and batteries should be offered for transport at a state of charge not exceeding 30 per cent of their rated capacity; or

2) The indicated battery capacity for lithium ion cells and batteries when offered for transport should not exceed 25 per cent.

While state of charge is indicated for packaged cells and batteries it was indicated that only the original manufacturer could definitively determine the state of charge when contained in equipment. Thus the indicated battery capacity is a practical recommendation for equipment. Others indicated that consistency of text with the other packing instructions is favorable to ease understanding. It was agreed that both options would be presented to the DGP. The group agreed to several other editorial amendments to the packing instructions.

3.3.3 Drafting of the note regarding state of charge limits and the editorial amendments would be left to the rapporteur and the secretariat. A revised draft of the amendments to the Technical Instructions would be circulated to the group.

3.4 **Transition period**

3.4.1 The group considered whether a transition period is appropriate to minimize disruptions to the supply chain associated with a state of charge requirement. Changes agreed to by the panel during DGP/29 would become effective 1 January 2025 observing normal approval procedures. It was noted that the next edition of the Technical Instructions and the IATA Dangerous Goods Regulations are normally available during the third quarter of 2024 leaving only a few months between publication and effect. ICAO indicated there are mechanism to communicate upcoming changes to the next edition of the Technical Instructions prior to publication. A number of ideas were circulated including a transition period during which the reduced state of charge would be a recommendation for both lithium ion batteries packed with equipment and contained in equipment. After the expiration of the transition, a reduced state of charge for batteries packed with equipment would become mandatory. The group did not come to any conclusions regarding whether a transition period is appropriate.

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# APPENDIX A

## THERMAL INCIDENT DATA RELATED TO AIRCRAFT OPERATIONS REPORTED THROUGH THE VOLUNTARY THERMAL RUNAWAY INCIDENT PROGRAM (TRIP)

Standards & Engagement

# TRIP Cargo Data

## Summary of data from 2017 - 2023

ICAO Energy Storage Devices Working Group
9 November 2023

Safety Science in Action™

# Current TRIP Participants

| | | |
|---|---|---|
| Air Canada | FedEx | Republic Airways |
| Alaska Airlines | Hawaiian Airlines | SkyWest |
| Allegiant | Horizon Air | Southwest Airlines |
| American Airlines | JetBlue Airways | Spirit |
| Ameristar | Omni Air International | United Airlines |
| Delta Air Lines | Piedmont | UPS Airlines |
| Emirates | PSA Airlines | USAF Air Mobility Command |
| Envoy | | |

Additional stakeholder groups involved in TRIP:  Air Line Pilots Association, Boeing, US Postal Inspection Service.

# Data constraints and limitations

1. Compilation of 715 incidents thru 09/30/2023.
2. 3+ years of tailored reporting.
   – Lithium Battery/Aviation specific.
   – Passenger / Baggage / Cargo.
3. Includes “near miss” / non-reportable incidents (segregated).
4. Increasing participation and data availability. **Includes incidents from FAA lithium battery incident summaries.**

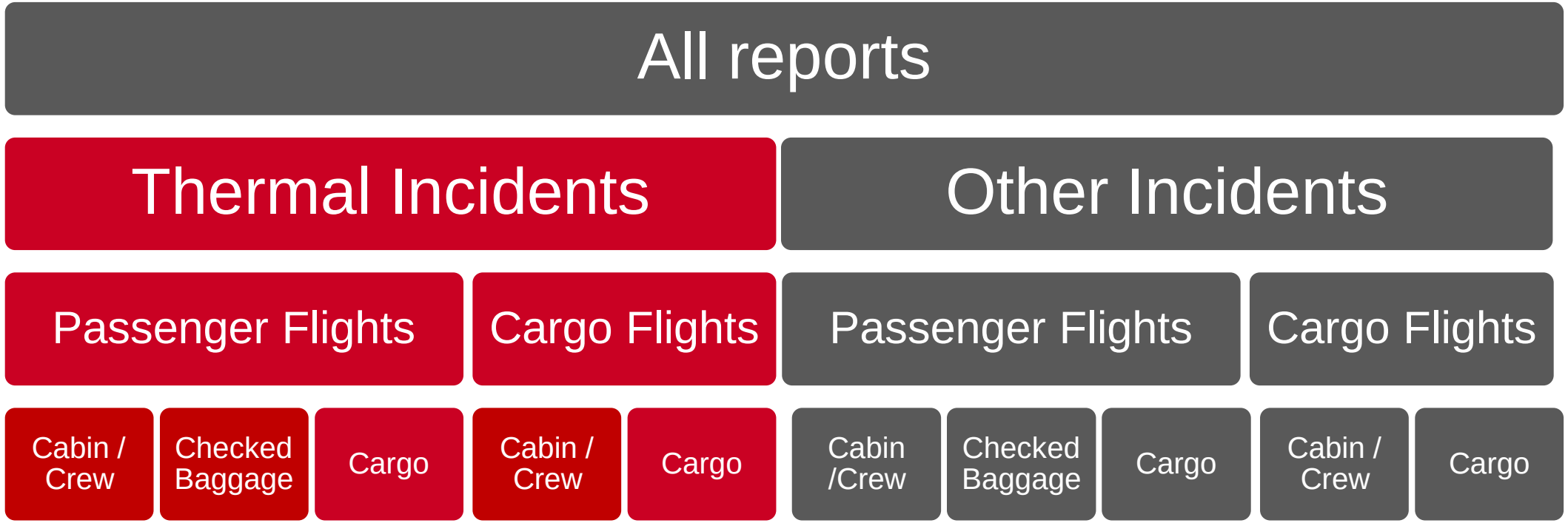
Subset of airline industry – not a complete accounting, is not the full story.

Incident data capture process has “gaps.”

- Source is the crew – priority to safety, not data capture.
- Device ownership, damage, etc. limit detailed data capture.
- Lack of forensic process and resources at airlines limits root cause.

Structural and operational changes due to Covid complicate trending & analysis.

# Data analysis framework

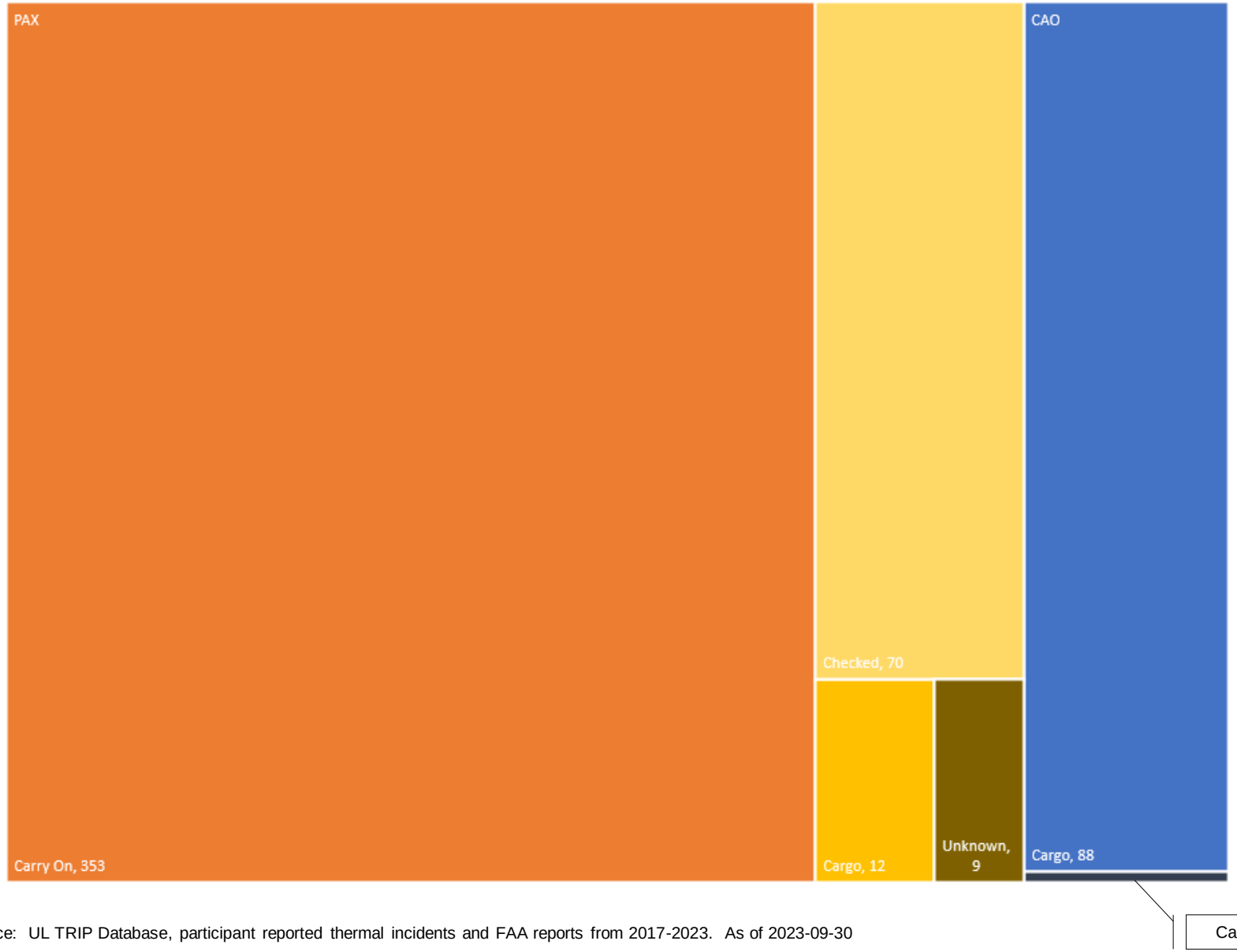


# All thermal incidents by carrier type and path, 2017-2023

537 thermal incidents

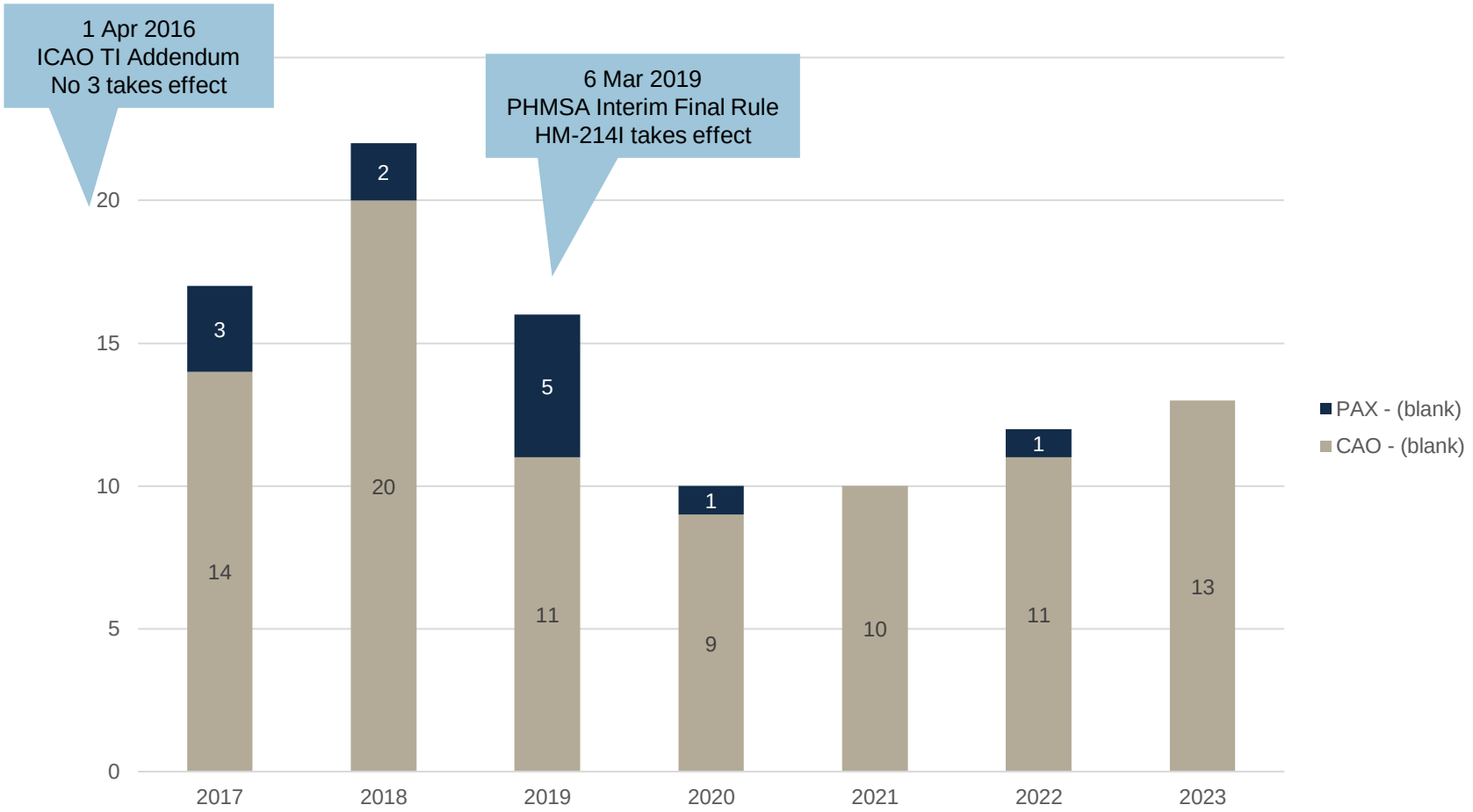
72 carriers + TSA

2017 - 2019 data include news and informal reports




Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

# Time series trend, cargo thermal incidents, 2017-2023



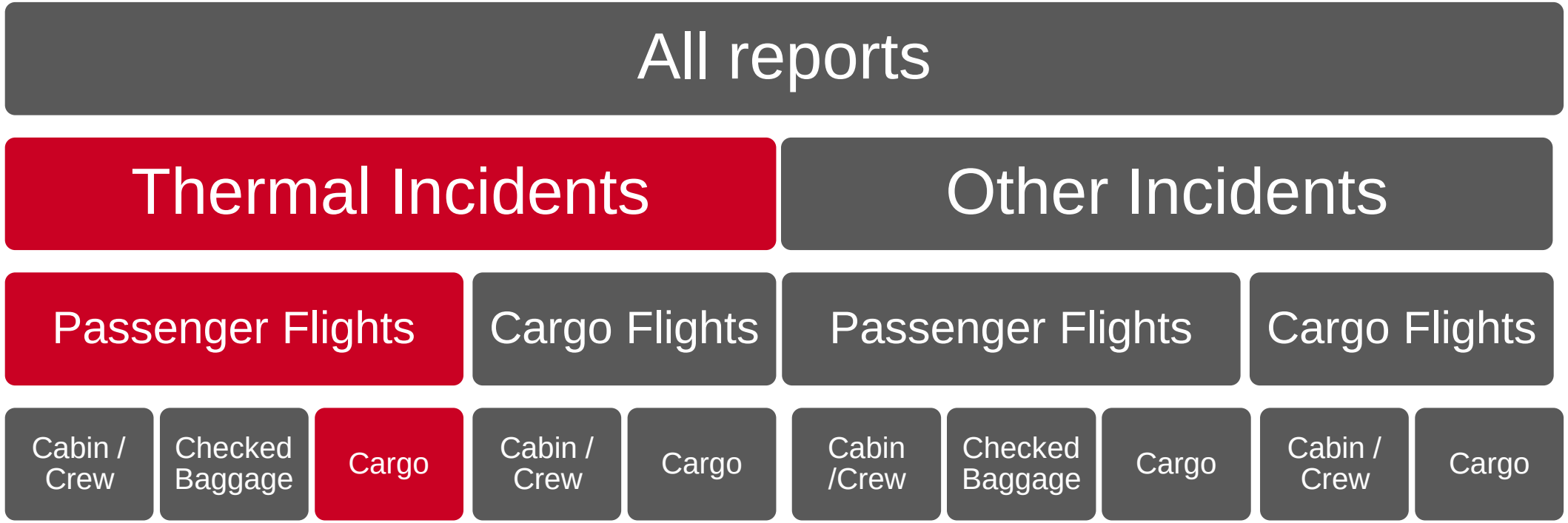

101 thermal incidents

Incidents shown are events that involve a “a fire, violent rupture, explosion, or a dangerous evolution of heat.”

*Swollen or damaged batteries and procedural issues are <u>not included</u> in this chart.*

Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

# Data analysis framework

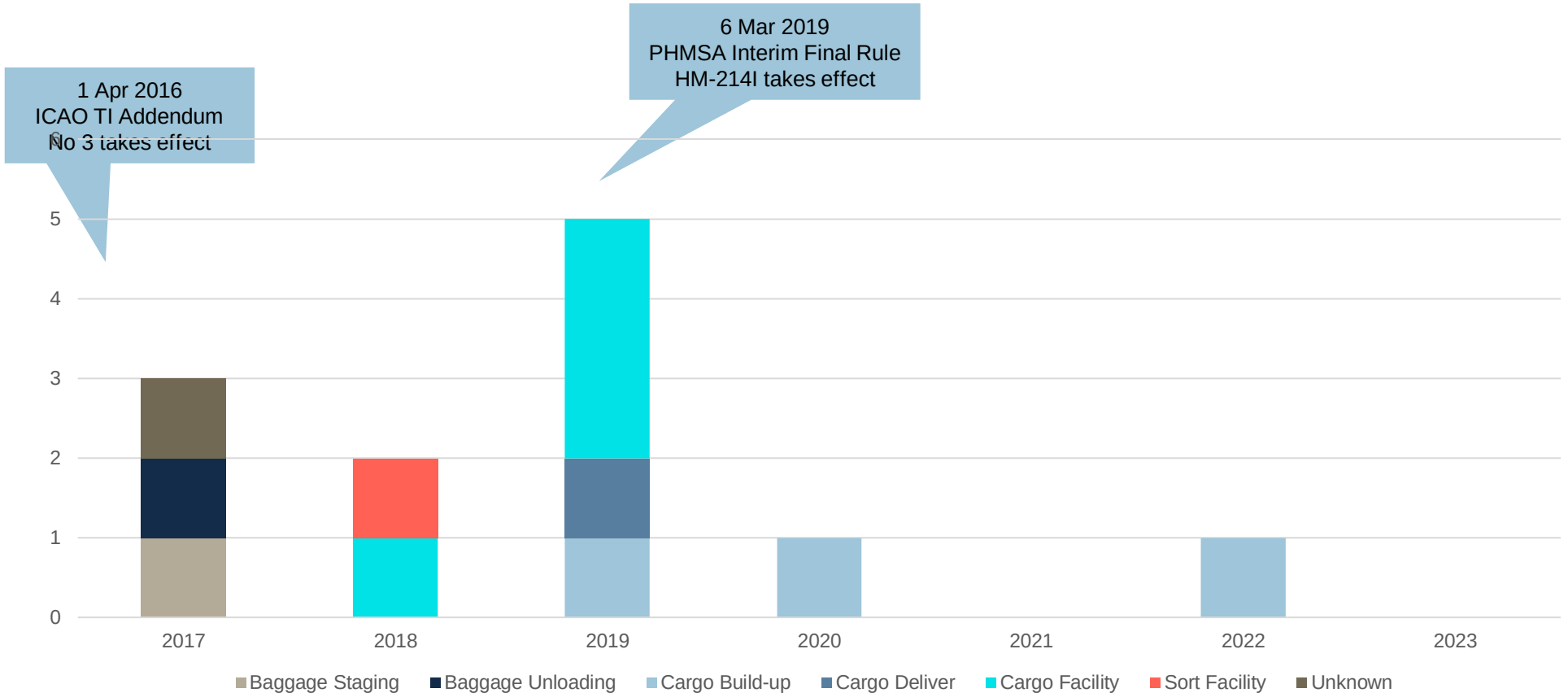


# Relevant rulemaking

- ICAO TI Addendum No 3, issued 15 Jan 2016
  - Lithium ion cells and batteries must be offered for transport at a state of charge not exceeding 30 per cent of their rated capacity. Cells and/or batteries at a state of charge greater than 30 per cent of their rated capacity may only be shipped with the approval of the State of Origin and the State of the Operator under the written conditions established by those authorities.

- PHMSA Interim Final rule HM-214I, issued 6 Mar 2019
  - The Pipeline and Hazardous Materials Safety Administration (PHMSA) issues this interim final rule (IFR) to amend the Hazardous Materials Regulations (HMR; 49 CFR parts 171-180) to (1) prohibit the transport of lithium ion cells and batteries as cargo on passenger aircraft; (2) require all lithium ion cells and batteries to be shipped at not more than a 30 percent state of charge on cargo-only aircraft; and (3) limit the use of alternative provisions for small lithium cell or battery to one package per consignment.

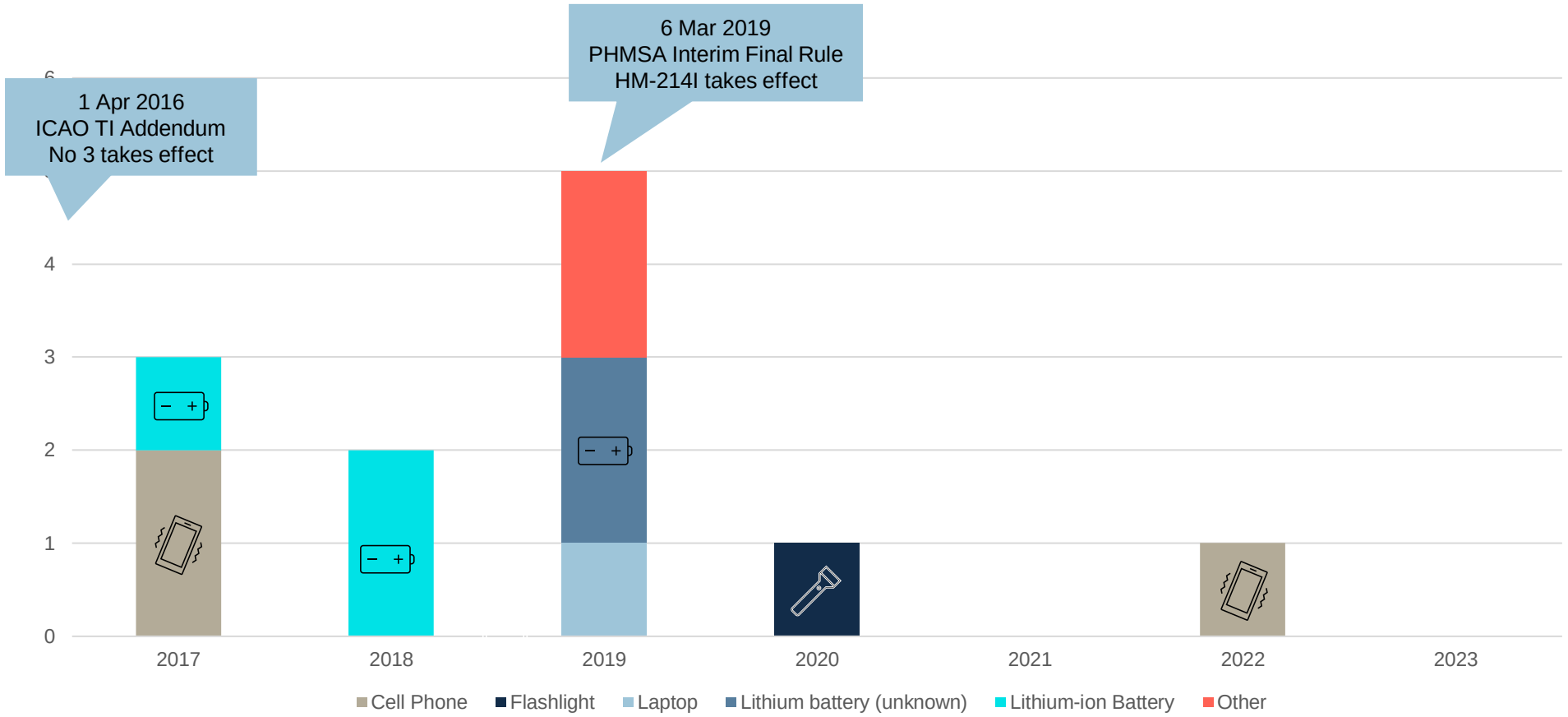
# Passenger flights, cargo incidents, by location, 2017-2023




No bulk battery incidents on passenger flights since PHMSA Rule HM-214I

Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

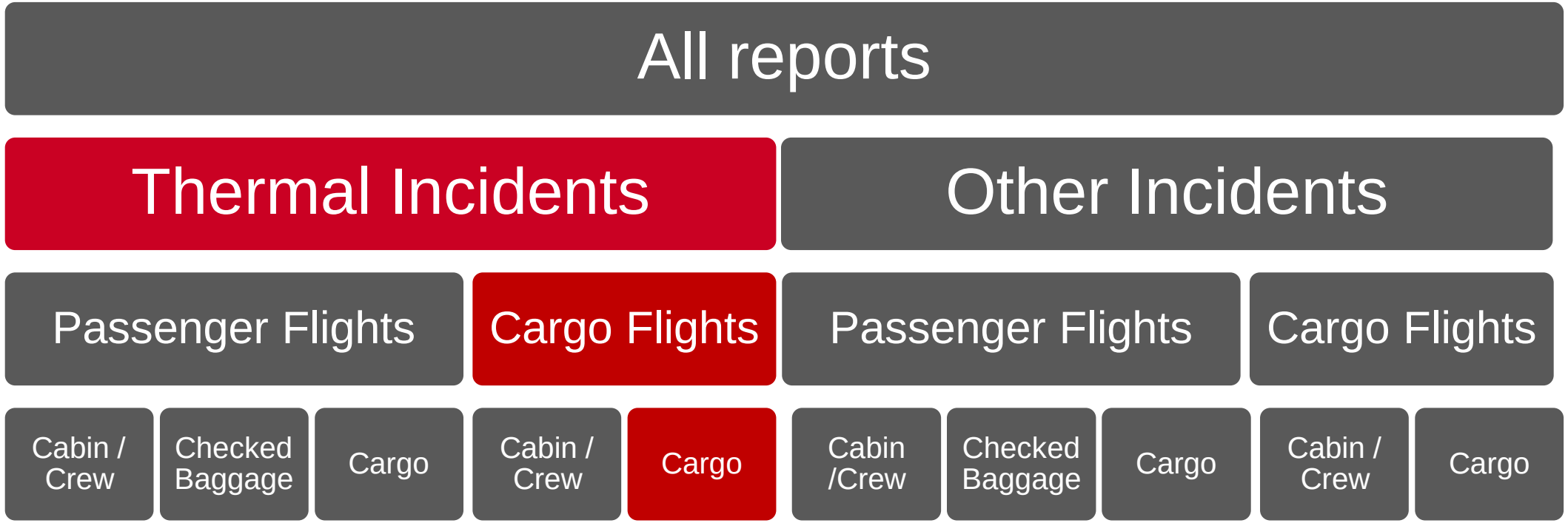
# Passenger flights, cargo incidents, by device, 2017-2023



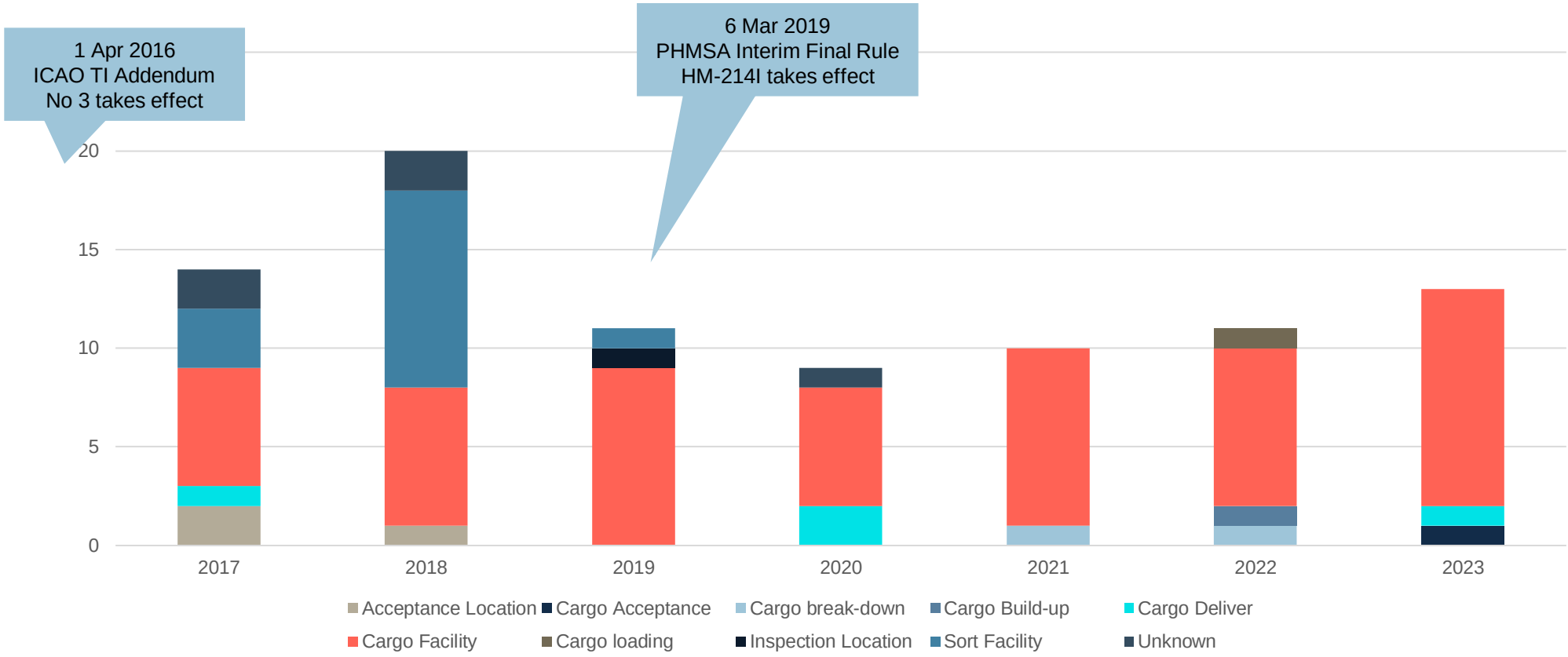

No bulk battery incidents on passenger flights since PHMSA Rule HM-214I

Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

# Data analysis framework



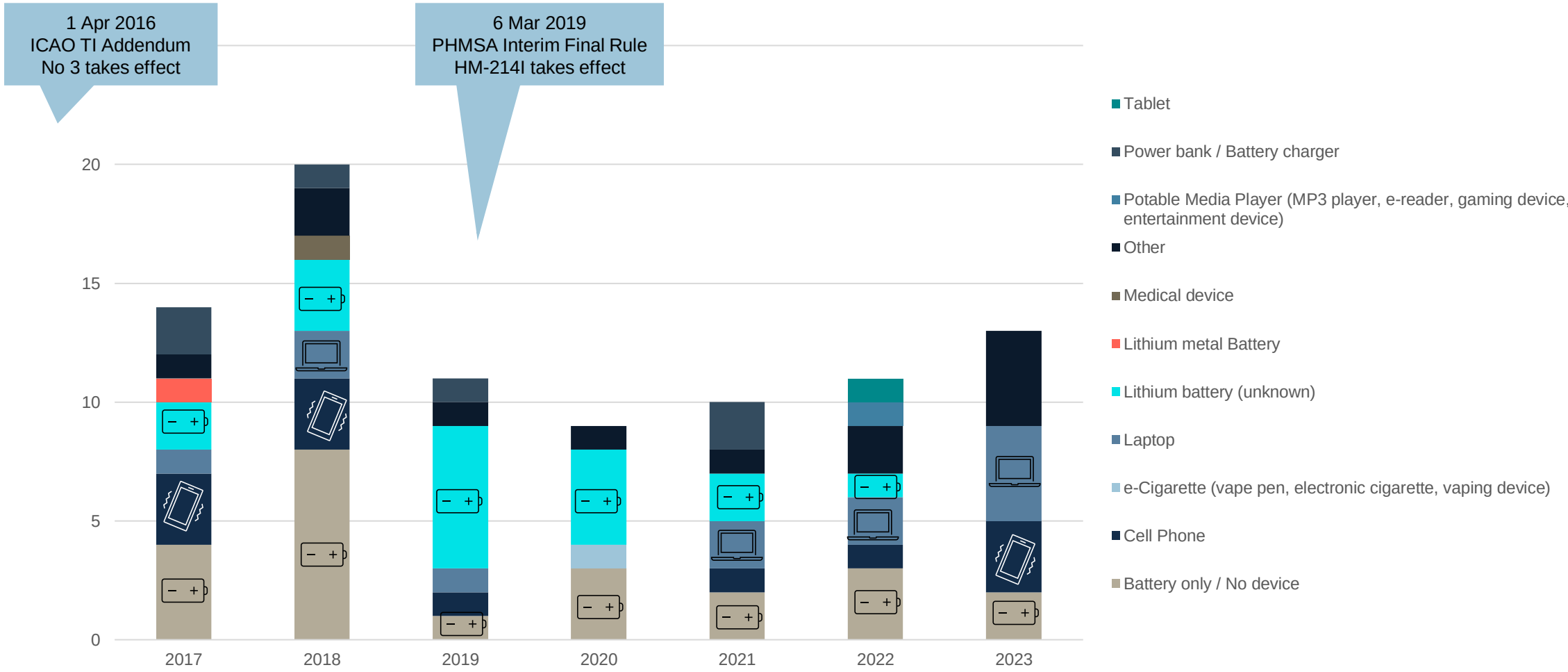
# Cargo flights, cargo incidents, by location, 2017-2023




No cargo incidents discovered on airplane.

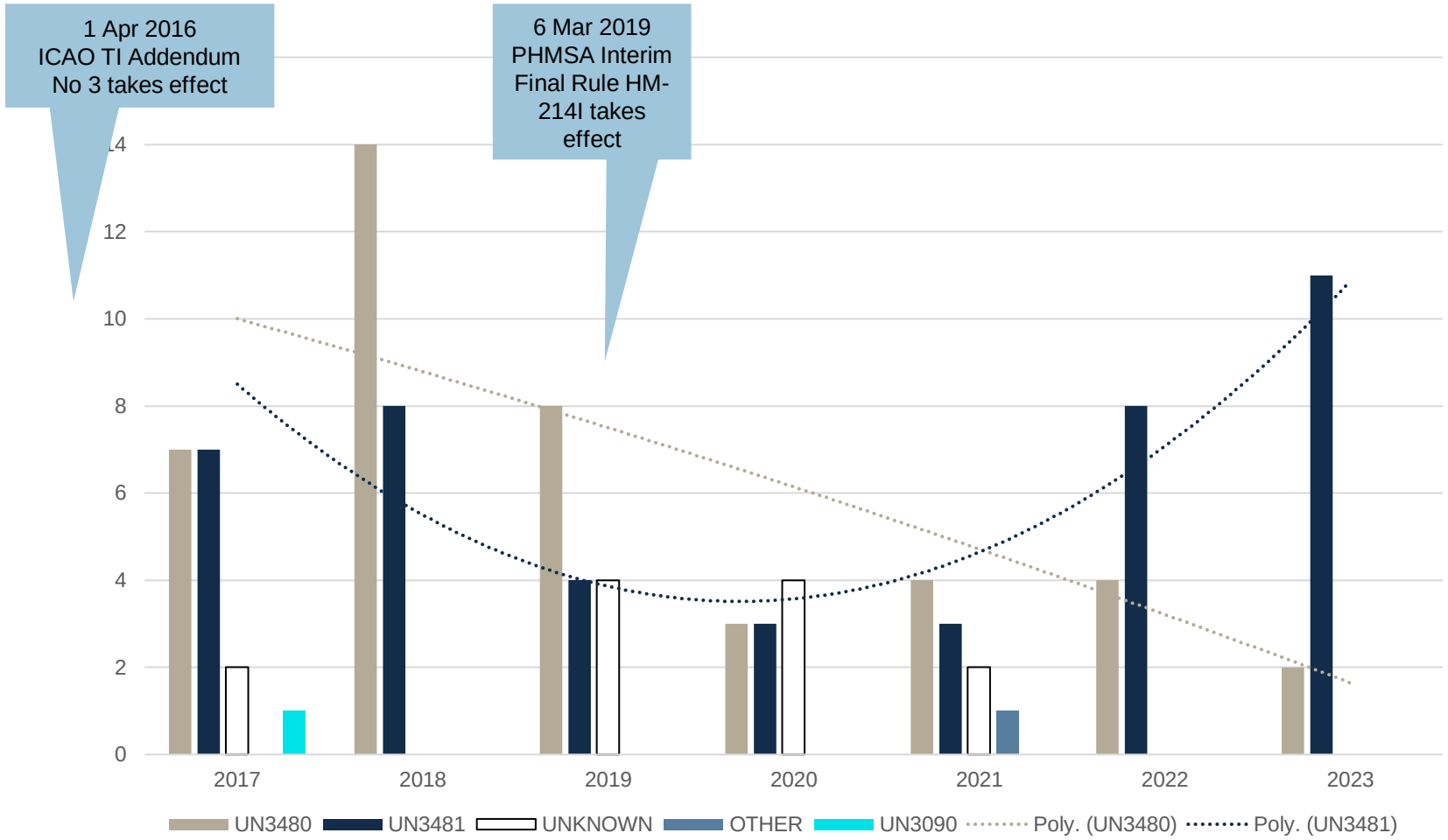
Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

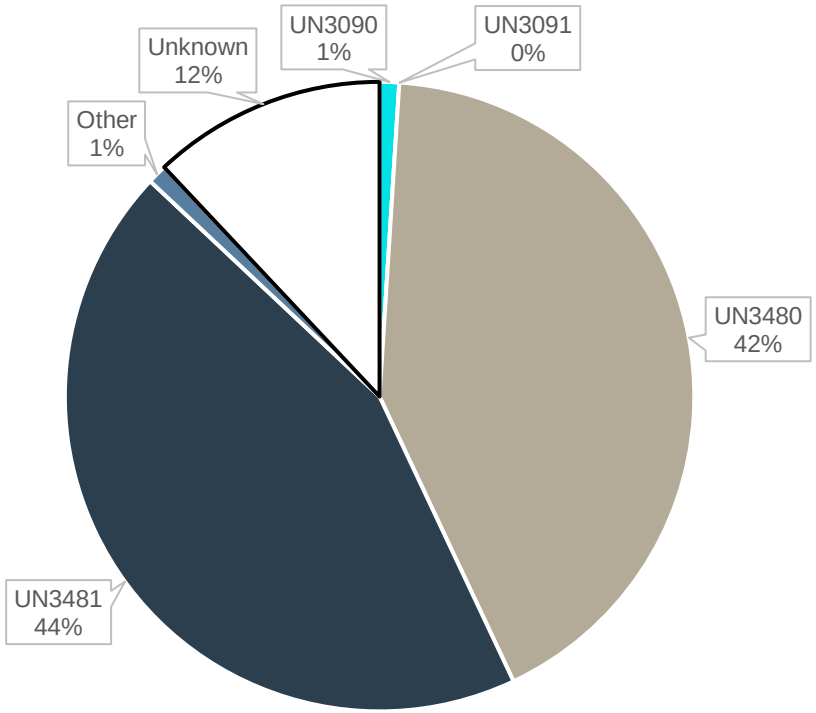
# Cargo flights, cargo incidents, by device type, 2017-2023




Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

# CAO cargo incidents, by UN classification, 2018-2023

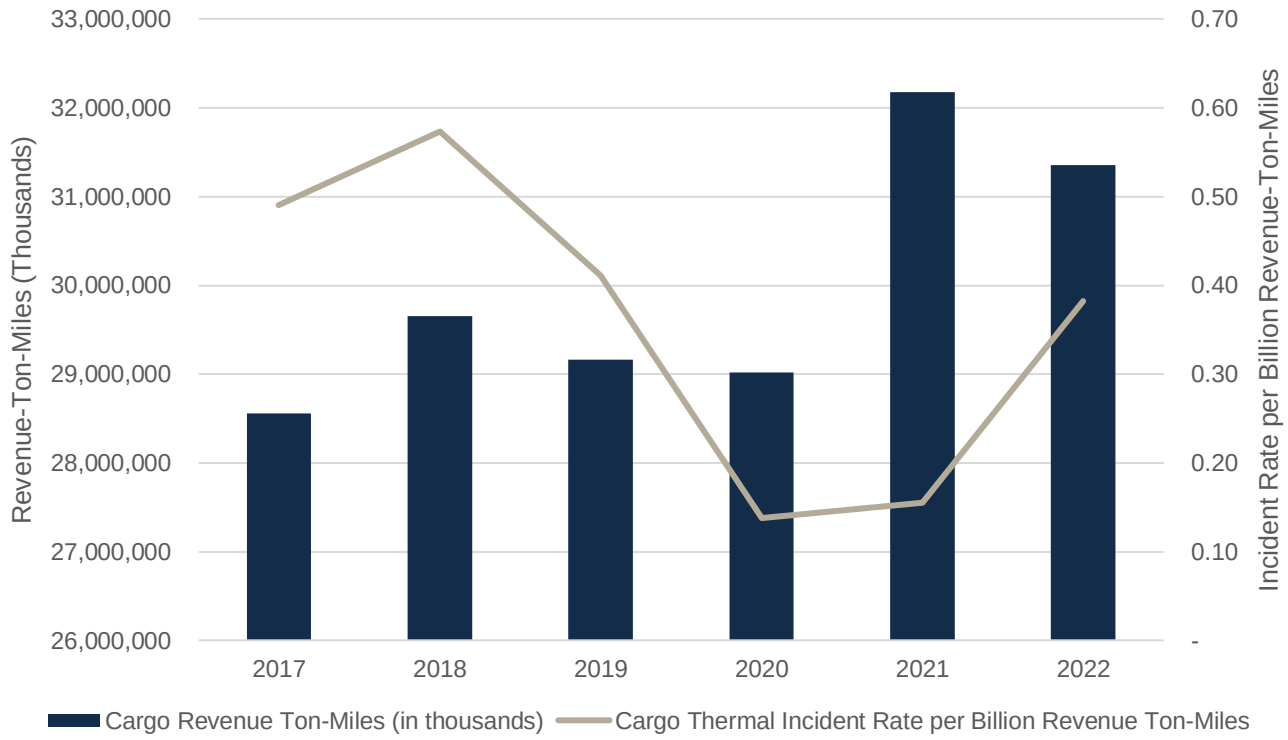



Source: UL TRIP Database, participant reported thermal incidents and FAA reports from 2017-2023. As of 2023-09-30

Standards & Engagement

# Cargo incident rate per billion revenue-ton-miles

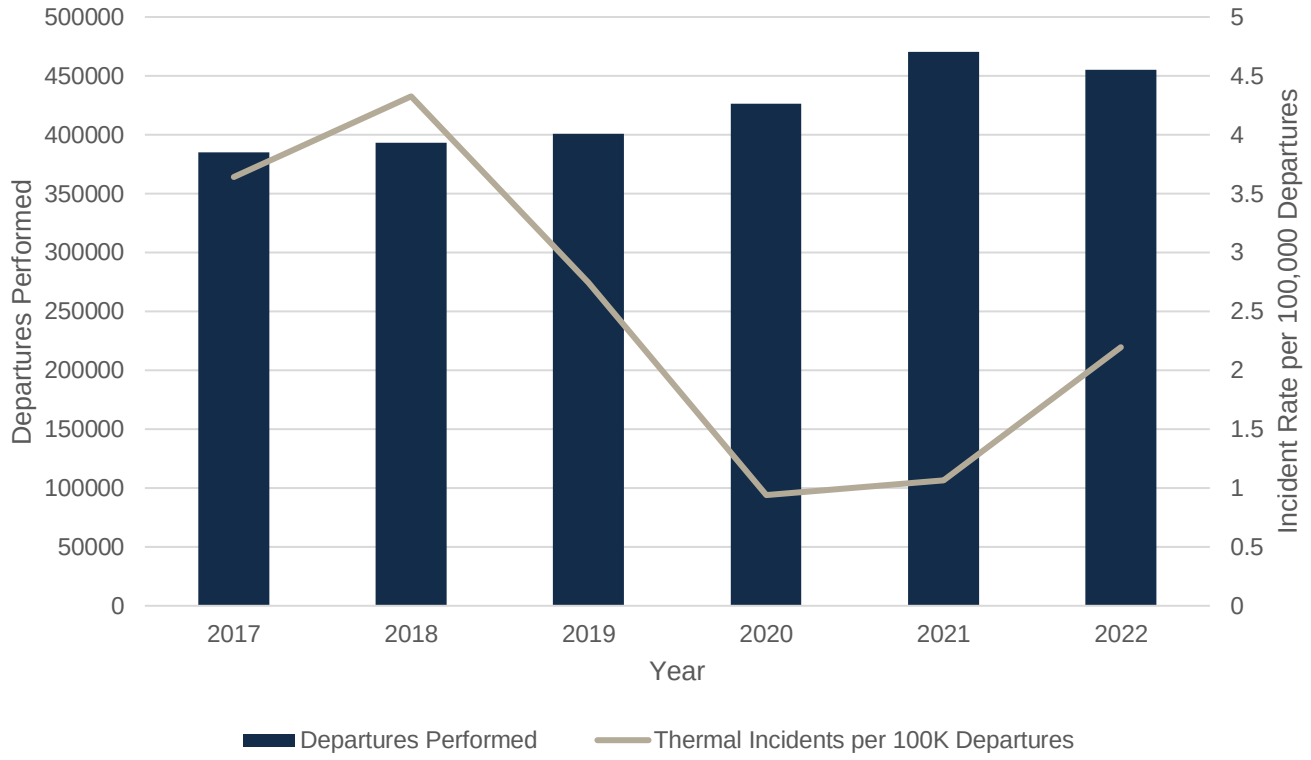



$$Incident\ Rate = \frac{Thermal\ Incidents}{Cargo\ Volume}$$

- TRIP participants only
- Cargo volume from Bureau of Transportation Statistics (BTS-100 tables)

Source: ULSE TRIP Database, participant and FAA reports, as of 2023-09-30.
Bureau of Transportation Statistics, BTS-100 data, accessed 2023-05-25

# Incident rate per 100,000 departures, CAO operations




$$Incident\ Rate = \frac{Thermal\ Incidents}{100{,}000\ CAO\ Departures}$$

- TRIP participants only
- Cargo volume from Bureau of Transportation Statistics (BTS-100 tables)

Source: ULSE TRIP Database, participant and FAA reports, as of 2023-09-30.
Bureau of Transportation Statistics, BTS-100 data, accessed 2023-05-25

# Insights

- **Cargo**
- 19% of incidents since 2017.
- Passenger flights with cargo
  - 7 of 12 incidents involve US mail, no incidents in 2022 or 2023
  - No incidents on the aircraft
- Cargo freighter operations
  - One cabin/crew incident
  - At least 44% UN 3481, during 2017-2023, up significantly
- Incidents declining for UN 3480 since 2017
- UN 3481 incidents hit a minimum in 2020/2021, increasing since then.
- Cargo incident rates rose in 2022, on a per revenue-ton-mile basis and per departure. This is a result of increased incidents with UN 3481 shipments.

# APPENDIX B

## DATA RELATED TO U.S. IMPORT-EXPORT DATA ON UN 3480/UN 3481/UN 3090

# ICAO Dangerous Goods Panel Energy Storage Devices Working Group

## 2022 U.S. Import-Export Data on UN3480/UN3481/UN3090 based on Harmonized Tariff System (HTS) and Harmonized Tariff Schedule of the United States

## November 9 - 10, 2023

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MOTOROLA SOLUTIONS
3M
ECHO
shindaiwa
INTERSTATE BATTERIES
asurion
KBI
BOSCH
Cirba Solutions
EASTPENN
Li-Cycle
TDK
SAGER ELECTRONICS
Microsoft
AMSAFE BRIDPORT
CELL-CON
makita
VARTA
Abbott
TOYOTA
call2recycle
Canon
Ford
Batteries Plus
Google
saft
HAZMAT
PHILIPS
ULTRALIFE
CHEMTREC
Fedco Batteries
THE RECHARGEABLE PRBA BATTERY ASSOCIATION
Cummins
YUASA
FDK
LG Energy Solution
ups
hp
DURACELL
LABELMASTER
MOBILE POWER SOLUTIONS
QuantumScape
partech
CellBlock
SAMSUNG
ENOVIX
amazon
maxell
Energizer
LUCID
Lenovo
gm
Integer
national power CORPORATION
Panasonic
umicore
TTI
Americase
BRIGGS&STRATTON
EnerSys
ENERGY ASSURANCE
Medtronic
FedEx
CSA GROUP
SONY
StanleyBlack&Decker
TORO
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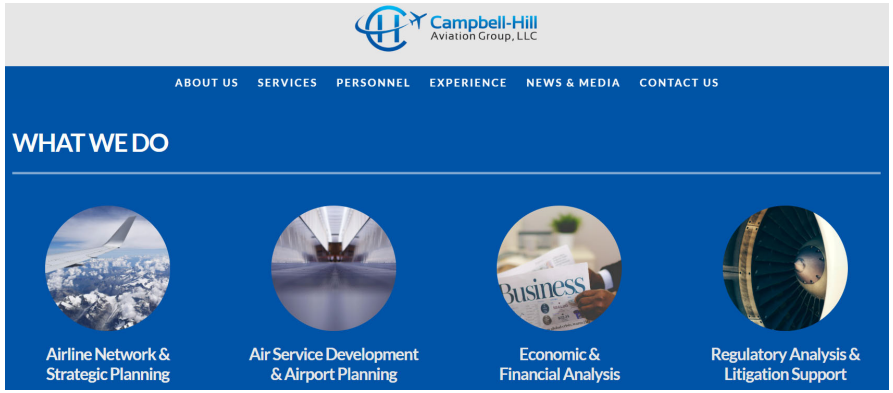
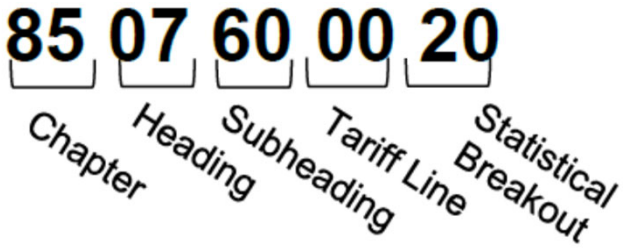
# PRBA and Campbell-Hill Aviation Group




- PRBA and Campbell-Hill Aviation Group have tracked since 2010 imports into the U.S. and exports/re-exports from the U.S. of lithium ion and lithium metal cells and batteries (UN3480/UN3090) and lithium ion battery-powered products (UN3481)
- Data are compiled from the U.S. Bureau of the Census trade data
- Census data identifies shipment value, weight, and number of products that enter/exit a U.S. point via air from/to a foreign point

# The Harmonized Tariff Schedule of the United States




- In this example of a full, 10-digit provision:
  - 6-digit subheading (8507.60) covers lithium-ion batteries
  - 00 indicates tariff line 8507.60.00, with a scope identical to subheading 8507.60
  - 20 indicates statistical breakout 8507.60.0020, covering lithium-ion batteries other than those of a kind used to propel electric vehicles

# The Harmonized Tariff Schedule of the United States – Cellular Phones

| Heading/ Subheading | Stat. Suf-fix | Article Description | Unit of Quantity | Rates of Duty 1 General | Rates of Duty 1 Special | Rates of Duty 2 |
|---|---|---|---|---|---|---|
| 8517 | | Telephone sets, including smartphones and other telephones for cellular networks or for other wireless networks; other apparatus for the transmission or reception of voice, images or other data, including apparatus for communication in a wired or wireless network (such as a local or wide area network), other than transmission or reception apparatus of heading 8443, 8525, 8527 or 8528; parts thereof: | | | | |
| | | Telephone sets, including smartphones and other telephones for cellular networks or for other wireless networks : | | | | |
| 8517.11.00 | 00 | Line telephone sets with cordless handsets | No | Free[8/] | | 35% |
| 8517.13.00 | 00 | Smartphones | No | Free | | 35% |

**HTSUS Classification**
Chapter 85
Heading 8517
Subheading 8517.13
Tariff Line 8517.13.00
Statistical Breakout 8517.13.0000

**Product Description**

**Duty Rates**
Column 1-General: the standard duty rate
Column 1-Special: rate under specific free trade agreements (none here because the standard duty rate is 0%)
Column 2: rate for countries not accorded "most favored nation" status (*e.g.*, Russia, North Korea, Cuba, etc.)

# 2022 Trade Value for U.S. Imports of Lithium ion Battery Powered Products (UN3481, UN3171)

| | | Total (millions) | Air (millions) |
|---|---|---|---|
| **U.S. Imports** | | | |
| Communication Equipment | | $122,439 | $100,205 |
| Notebook and Handheld Computers | | $53,680 | $45,332 |
| Audio & Video Equipment | | $9,250 | $5,110 |
| Hand Power Tools | | $6,040 | $191 |
| Small Electrical Appliances* | | $3,122 | $1,029 |
| Lawn & Garden Equipment* | | $1,614 | $1 |
| Electric Vehicles* | | $12,737 | $80 |
| Other Electronic Products | | $7,633 | $3,406 |
| | | | |
| **Combined Totals** | | **$216,514** | **$155,354** |

* New categories added in 2022

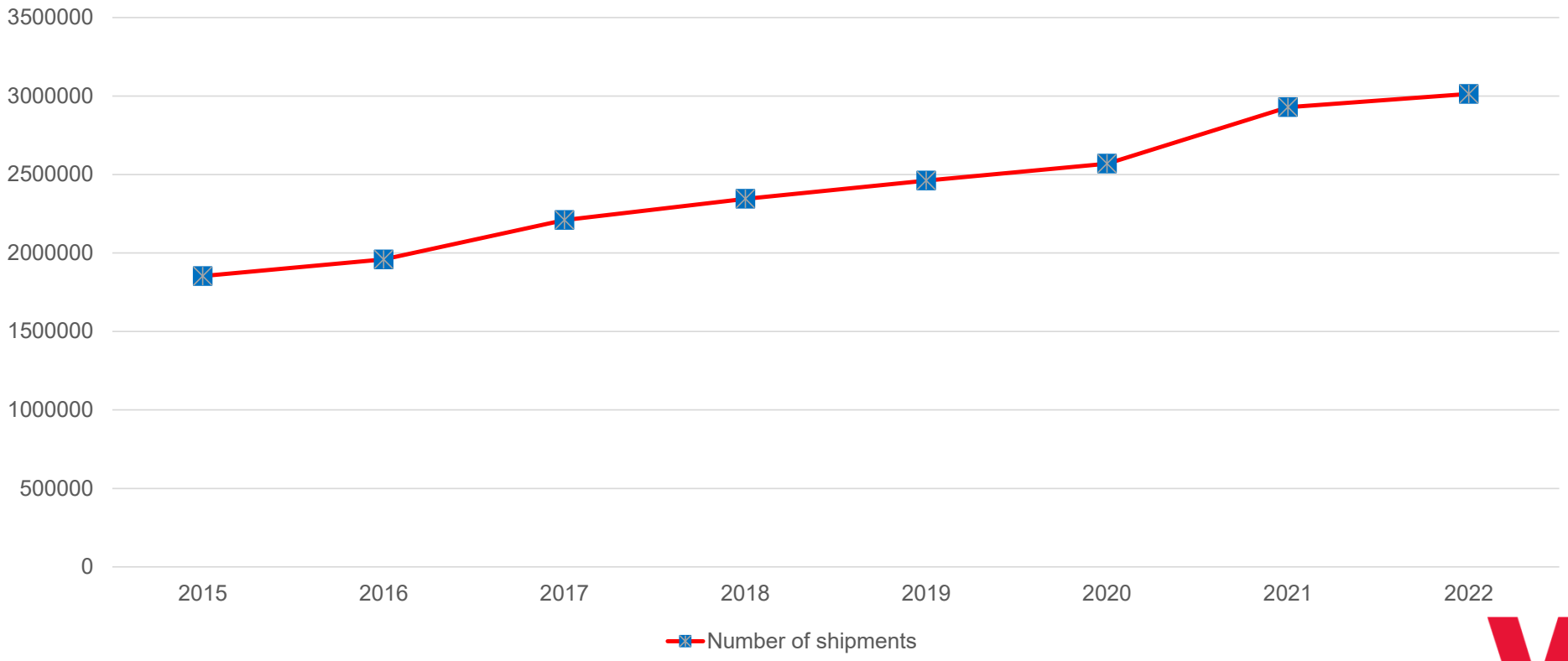
Source: U.S. Bureau of the Census trade data and Campbell-Hill Aviation Group

| | Units (millions) | Shipments (000) |
|---|---|---|
| **U.S. Imports** | | |
| Communication Equipment | 423.1 | 1,003.4 |
| Notebook and Handheld Computers | 80.9 | 964.9 |
| Audio & Video Equipment | 29.8 | 116.8 |
| Hand Power Tools | 0.9 | 15.0 |
| Small Electrical Appliances* | 18.0 | 52.9 |
| Lawn & Garden Equipment* | 0.0 | 0.3 |
| Electric Vehicles* | 0.0 | 8.1 |
| Other Electronic Products | 19.1 | 141.5 |
| **Combined Totals** | **571.8** | **2,302.9** |

# U.S Air Trade Volumes for UN3481/ UN3171 Products (2022)

* New categories added in 2022

# UN3481 Imports to and Exports/ Re-Exports from U.S. by Air (2015 – 2022)




*Source: U.S. Bureau of the Census trade data and Campbell-Hill Aviation Group*

# Medical Devices and Lithium ion Batteries

- Implantable medical devices with lithium ion batteries have SOC-related specifications as part of device manufacturing process approved by U.S. Food and Drug Administration (FDA)
- If 30% SOC limit is adopted, specification and manufacturing change would require FDA review – a 180-day process
- Any changes to product designs with potential performance impacts also subject to FDA review
- Extended shelf life periods at low states of charge could lead to a performance impact, latent failures, safety issues (e.g., overdischarge)

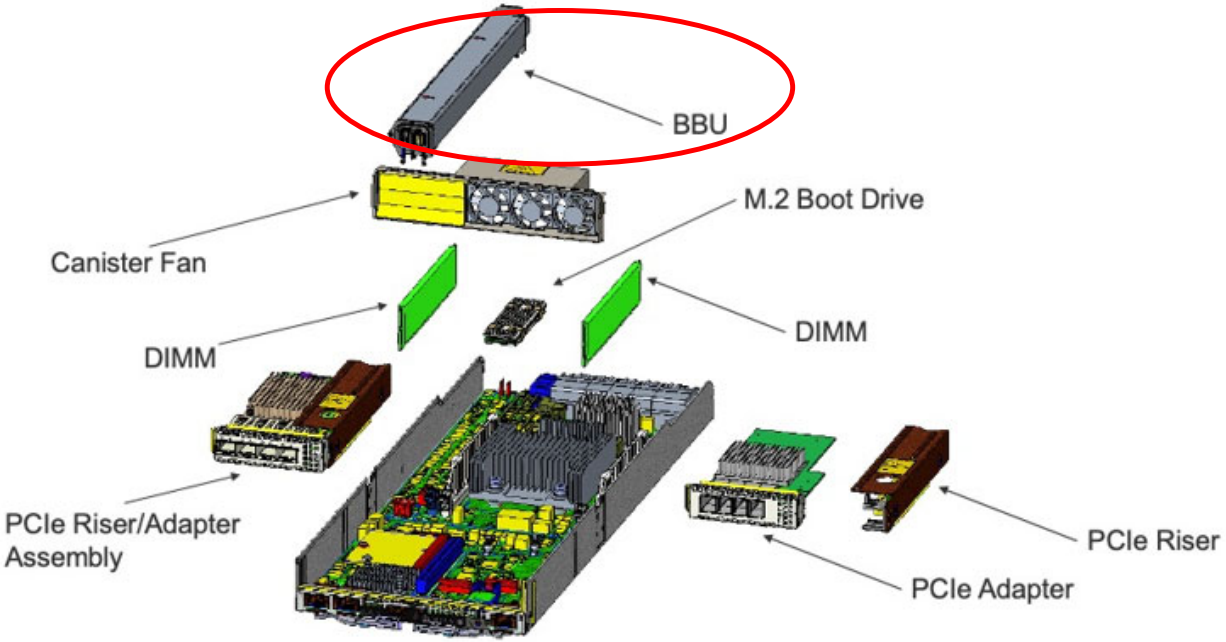
# Medical Devices and Lithium ion Batteries

- Low capacity devices such as diabetes continuous glucose monitors (CGM) utilize very small lithium ion batteries
- Devices currently shipped at 100% SOC with a 6 month shelf life
- Current draws will quickly deplete battery if stored at 30% SOC
- At 30% SOC shelf live drops to less than 2 months

# Enterprise IT Equipment and Lithium ion Batteries

- Enterprise IT Equipment: Include servers, mainframes, storage, appliances: delivers connected digital and secured services
- All have lithium ion batteries as backup power source (“BBU”)
- Cannot control SOC of lithium ion battery
- Batteries are embedded into rack drawers inside computer rack with complex cabling
- Typical computer rack is 60 cm wide, 114 cm deep, 200 cm tall
- A fully configured rack can weigh up to 1100 kg

# Enterprise IT Equipment and Lithium ion Batteries

# Summary

- The number of UN3481 U.S. air shipments (imports to and exports/re-exports from U.S.) increased from 1,853,000 to 3,013,000 between 2015 – 2022
- 2022 trade value for U.S. air imports of lithium ion battery-powered products (UN3481, UN3171) was $155.3 billion
- Cargo incident frequency did trend downward per TRIP data between 2017 and 2021 even with increased cargo volumes
- 2022 and 2023 has seen a small increase in incidents, no incidents in cargo hold in 2023 (as of November 1st)

# Summary

- Lithium ion batteries contained (embedded) in equipment are uniquely different than lithium ion batteries packed with equipment
- The ESD WG has not fully considered the implications of requiring a 30% SOC limit on products like life-saving medical devices and enterprise IT equipment
- A blanket carve-out from SOC limits is needed for all life-saving medical devices – that includes lithium ion batteries packed with and contained in equipment

# Summary

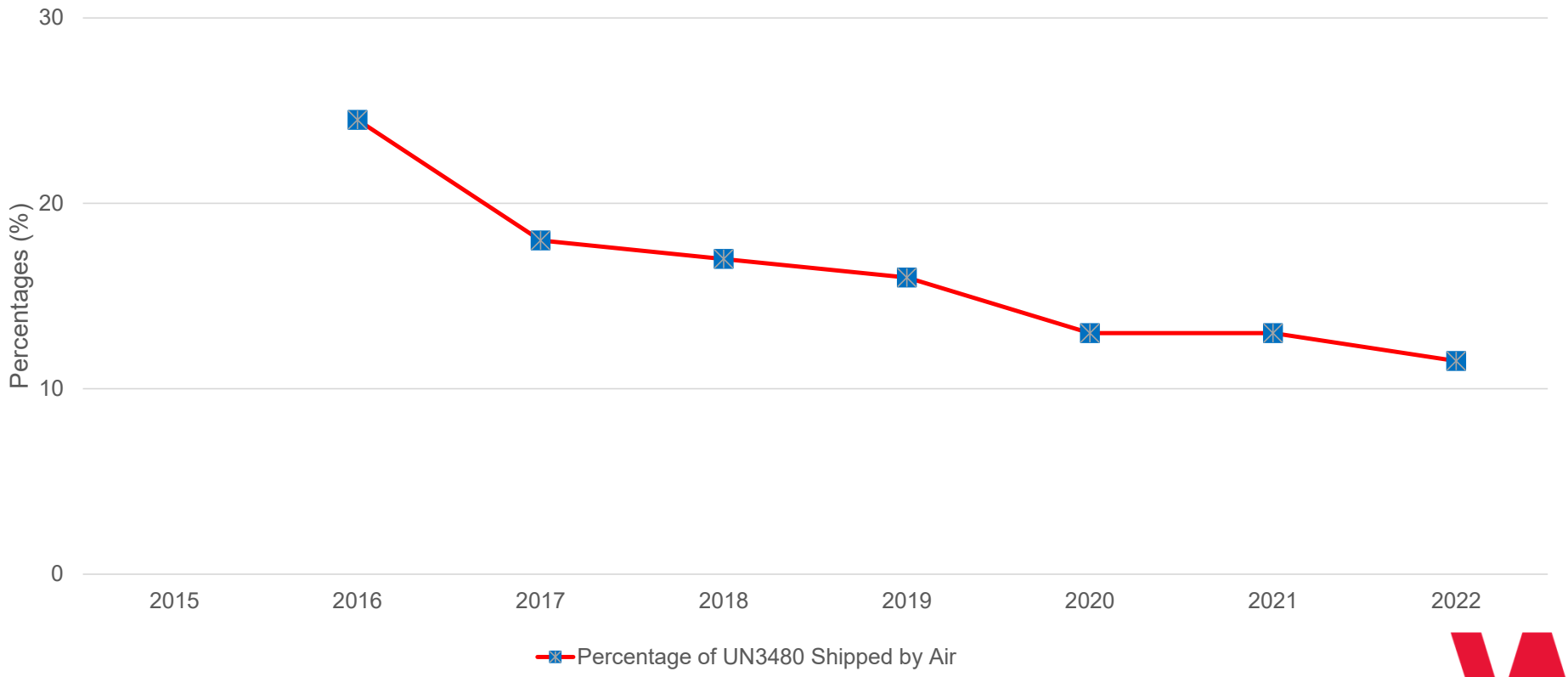
- State of charge will play a significant role in how lithium ion batteries are regulated under the UN's new lithium battery hazard-based classification system requested by the ICAO Secretariat
- Changes to the ICAO TI in 2025 and again in 2027 (or 2029) will create more confusion, substantial non-compliance
- Any new regulations on SOC should provide a one-year transition period (i.e., effective date January 1, 2026)

# 2022 and 2021 Lithium ion Battery (UN3480) Import/Export Air Trade Data

| 2022 Data | | | |
|---|---|---|---|
| | Units (millions) | Shipments (000) | Units per Shipment |
| **U.S. Imports** | | | |
| Lithium ion Batteries | 63.6 | 40.0 | 1,588 |
| | | | |
| | | | |
| **U.S. Exports and Re-Exports** | | | |
| Lithium ion Batteries | 4.3 | 17.0 | 255 |

| 2021 Data | | | |
|---|---|---|---|
| **2021 Data** | Units (millions) | Shipments (000) | Units per Shipment |
| **U.S. Imports** | | | |
| Lithium ion Batteries | 196.4 | 81.3 | 2,416 |
| | | | |
| | | | |
| **U.S. Exports and Re-Exports** | | | |
| Lithium Ion Batteries | 6.1 | 18.1 | 335 |

# Overall Percentage of UN3480 Imports to and Exports/Re-Exports from U.S. by Air (2016 – 2022)




*Source: U.S. Bureau of the Census trade data and Campbell-Hill Aviation Group*

# APPENDIX C

## IMPACT ON INDUSTRY IF REQUIREMENT IMPLEMENTED PROVIDED BY MDTC

MDTC
Medical Device Transport Council

November 8, 2023

Mr. Teun Muller
ICAO Dangerous Goods Panel Chairman
Ministry of Infrastructure and the Environment
Directorate-General for Mobility Division for Civil Aviation
Plesmanweg 1-6
P.O. Box 20904
2500 EX The Hague, Netherlands



**Re: Implications of Potential ICAO DG Panel Proposal to Limit State of Charge on Medical Devices (WP/6)**

Dear Mr. Muller:

The Medical Device Battery Transport Council (MDTC) is a coalition of medical device manufacturers that advocate for responsible regulations governing the transportation of medical devices and the lithium batteries that power them. The MDTC works toward achieving its objectives by engaging regulators and other stakeholders to develop regulations that address critical safety needs without compromising the ability of patients to receive these life-saving medical devices in a timely manner.

The Medical Device Transport Council is extremely concerned with the proposal to limit the State of Charge (SOC) for lithium ion batteries contained in equipment in the DGP29 Working Paper 6. If adopted, it will have serious impacts on the ability to ship medical devices needed for lifesaving and life-sustaining purposes. The proposal ignores important patient safety considerations.

The medical device community produces state-of-the-art products that are already heavily regulated by FDA and other national health regulatory agencies to the highest standards of safety and effectiveness. The MDTC is not aware of a single aviation incident involving lithium battery-powered medical devices, nor have ICAO's proposals undergone any risk analysis to demonstrate that these changes would improve flight safety. To the contrary, the US Government has consistently expressed bipartisan concerns about the public health risks of restricting air shipment of medical device batteries and has allowed for exemptions for life-saving medical device batteries to be flown on passenger flights.

Medical device companies ship their lithium ion battery-powered medical devices to patients and hospitals primarily via aircraft due to the time-critical nature of patient care. The lithium-ion batteries in these devices need to be shipped at or near 100% SOC to allow for immediate use. Medical devices shipped at 30% SOC or lower will not have sufficient shelf life to go from finished manufacturing to the destination hospital with enough charge remaining to perform initial functionality tests. Without confirmation of device functionality, surgery cannot proceed. Further, hospitals and clinics often do not have the resources or specialized equipment needed to recharge devices and, even if the necessary equipment is present, many devices take hours to charge, resulting in delayed or cancelled medical procedures.

A disruption to the supply chain poses serious threats to public health. Patients need timely access to life-critical devices such as defibrillators, neuromodulators, and heart pumps. Wearable defibrillators that protect patients from sudden cardiac arrest are most often shipped by air because it is critical that patients are fitted as soon as possible. For every minute that a patient does not have access to a wearable defibrillator, the risk of cardiac arrest increases.

Lithium-ion batteries can also be permanently damaged if the SOC drops to 0% for an extended period and shipping a device with less than 30% SOC increases the likelihood of such an occurrence since devices may be stored for months at a time. Not all medical device battery packs have permanent undervoltage protection, and this can result in medical devices stored at < 30% SOC for prolonged periods of time to be unusable when they arrive to their destination.

If stored at 0% SOC for one month, lithium-ion batteries used for devices like neuromodulation implants can permanently lose up to 5% capacity. For neuromodulation implants charged to 100% SOC, the typical shelf life is about 6 months before the battery reaches 0% SOC and needs to be recharged. However, if the SOC is initially 30% or less, shelf life is reduced to only 1-2 months. Storing devices beyond this duration can permanently damage the battery with a measurable loss in capacity.

Many medical devices are fitted with wireless communication capability which uses battery power. These devices must be active and paired with an interrogation device to wirelessly determine the SOC. Implantable devices are not active while in the supply chain, and under the current ICAO Packing Instructions, they are forbidden from being active while in air transit. These devices often require a mechanical means of activation that cannot be achieved while they are in their sterile package. For these devices it is impossible to verify the state of charge without impacting the sterility of the device.

Due to security reasons, many devices must be specifically paired to an interrogation device, individuals in the supply chain typically do not have access to these interrogation devices. Certain devices that can be charged via wireless means become activated during the recharge process. Many of these devices cannot be deactivated without breaching the sterile or other tamper evident packaging.

Once a medical device is placed in a sterile package, it is often impossible to reduce the state of charge, other than that associated with the normal discharge rate. For medical devices, in particular those that are sterilized (including implantable devices), there may be no practical means to deplete the state of charge while the device remains in its sterile or tamper evident packaging.

It is also important to note that medical device manufacturers are required to ship medical devices for forensic analysis. Regulatory bodies mandate that the device is not tampered with prior to appropriate analysis and specify a timeline to complete the analysis that requires air transport as the mode of shipment. As a result, the devices cannot be discharged prior to transport.

If the 30% SOC restriction is adopted for air shipments of lithium-ion battery-powered medical devices, significant changes would need to be made throughout the medical device industry, including:

- **Recharging at the Hospital Prior to Surgery.** Recharging can take between one and twelve hours depending on the device. Devices are often sent via overnight service for morning procedures, adding recharge processes from below 30% SOC could result in unnecessary delays to procedures.

- **Recharging Post Surgery**. These devices are intended to be implanted with a full or near full state of charge. The recharging systems are not sterile, and recharging on an unhealed wound

can cause infection. Regarding the recharge process, implantable rechargeable devices are recharged using external wearable recharging systems. These systems use wireless technology to charge the implanted device through the skin. The link below provides a brief overview of the components to one of our systems and a video that describes the recharging process. https://www.medtronic.com/us-en/patients/treatments-therapies/spinal-cord-stimulation-chronic-pain/life-with-scs/recharging-device/intellis.html

- **Manufacturing Process and Device Change**. Medical devices are often not currently manufactured to a state of charge of <30%. As such, both device design and manufacturing processes will require to be changed. This will require significant effort and will often involve testing and validation to ensure that the device maintains suitable levels of safety and efficacy.

- **Changing the device itself to allow for an accurate way to determine the 30% SOC**. Unlike popular consumer electronic devices, many medical devices, including implantable devices, do not have displays that allow an easy measure of SOC. Without an effective way to verify SOC, these devices would have to be shipped near 0% SOC, which would further exacerbate the recharging issue and may ultimately damage the device.

- **Device Activation During Charging**. Certain medical devices that are charged through wireless means become activated during the recharge process. Many of these devices cannot be deactivated without physical access to the device. This is impossible for most medical devices as they are packaged in either sterile or tamper evident packaging.

- **Impacts on Shelf Life**. Due to the various challenges related recharging, discharging, and verifying the state of charge for devices while in the supply chain, many will require to be shipped from the manufacturer to distribution centers at or below than thirty percent state of charge to be subsequently shipped via air. This will significantly reduce the shelf-life of many devices. For certain devices, storage at less than thirty percent state of charge may reduce shelf life by more than sixty percent.

- **Regulatory Approval/Authorization Impacts**. Changes to device design and manufacturing processes may have an impact on health regulatory authorizations or approvals. It is possible that managing these approvals/authorizations could take significantly longer than the implementation period of new rules and have the unintended result of a de facto ban on the air transport of certain medical devices.

- **Risk of Deep Discharge.** Managing devices at less than thirty percent state of charge will increase the risk of batteries reaching a state of deep discharge. This can result in permanent capacity loss to certain batteries or the increased risk of gas generation and internal short circuits due to copper dissolution within the cell.

Lastly, medical devices are required aboard passenger-carrying aircraft as company owned materials (COMAT) to address circumstances where passengers or crew experience medical emergencies. Airlines not only carry the devices in the passenger cabin but must transport them as cargo to support operational requirements and avoid unnecessary grounding of the aircraft when replacement devices are needed. Requiring these medical devices to be shipped at the lowest state of charge would have serious implications for airlines being able to ship equipment including defibrillators and patient monitoring and communication devices.

If adopted, these provisions will have a significant impact to the medical device industry. Medical device manufacturers and distributors will be forced to re-evaluate and manage device safety and efficacy characteristics, manufacturing and distribution processes, and health regulatory approvals or authorizations. For devices that must be manufactured and distributed below thirty percent state of charge to be shipped by air, the shelf life will be reduced, which will result in increased e-waste and increased cost of the medical devices which, in turn, will cause an increase in the cost of health care and reduce industry's ability to efficiently deliver patient care.

**Ability to Ship when Needed Urgently**

Medical devices in certain circumstances need to be shipped urgently for lifesaving and life-sustaining purposes to support geographical locations that are not typically serviced by cargo aircraft. The current requirements make acquiring approvals for the transport of these life-saving devices extremely difficult, and in cases where the destination is not regularly serviced by cargo aircraft, there may not be a competent authority with the ability to issue an approval.

It should be made clear that medical devices and their batteries can be shipped at 100 % SOC on passenger aircraft for urgent medical need in circumstances where other forms of transport (including cargo aircraft) are impracticable. One possible way to address these concerns is to remove the medical device approval from A201 and to create a new standalone special provision for medical devices and their batteries to cover both transport on passenger aircraft and at a SOC greater than 30%. This would alleviate any confusion over the original intent of A201 and provide much needed clarification. We are hoping this could be done as a flimsy based on discussions during the DGP meeting.

If you have any questions concerning our request, please do not hesitate to contact me at (202) 637-8024 or by email at Steve.LaPierre@bsci.com. For additional information on the MDTC, please visit www.mdtc.org.

Sincerely,

Steven LaPierre
1455 Pennsylvania Ave, NW
Suite 925
Washington, DC 20004

# APPENDIX D

# CONSIDERATION OF COMMENTS ON EXTENDING A STATE OF CHARGE LIMIT TO LITHIUM ION BATTERIES PACKED WITH AND CONTAINED IN EQUIPMENT PROVIDED AT DGP/28

## 1. INTRODUCTION

1.1 The working group on energy storage devices met virtually on 19 September 2023. During this meeting the working group agreed to submit to the DGP a working paper and two information papers that detail the results of its analysis on the transport of lithium batteries packed with and contained in equipment (See DGP/29-WP41, DGP/29-IP/1, and DGP/29-IP/2). The Secretariat explained that the proposals from DGP/28 that proposed state of charge limits for lithium ion batteries packed with equipment and contained in equipment would be resubmitted for consideration during DGP/29 (see DGP/29-WP/6). The working group recognized that those proposals were not fully mature and outstanding comments remained. Therefore, the working group decided to reconsider the DGP/28 comments (see DGP/28-WP/59; Section 4.3 and Appendix B) with the goal of resolving those comments where possible to provide the Panel the information necessary to make a fully informed decision.

1.2 The working group separated the DGP/28 comments into discrete themes and identified the available information that could be considered to address the comments. The working group also recognized that any potential amendments based on WGP/29-WP/6 would need to be further developed should the Panel agree to amendments to the Technical Instructions. The comment themes identified include:

1) data;

2) incident reports;

3) economic impact and market feasibility;

4) regulatory compliance liability for shipper other than the OEM;

5) lower SOC could lead to cell degradation;

6) provisions to facilitate transport of certain lifesaving/life-sustaining medical devices; and

7) revisiting assumptions from what we have learned.

## 2. ANALYSIS

2.1 The panel over the last several years has reviewed extensive data involving lithium batteries and equipment including safety testing of various sizes, form factors and chemistries of lithium batteries forced into thermal runaway at various states of charge, effectiveness of aircraft fire suppression systems, trends in lithium ion battery energy density, and air transport volumes. This yields a clear

summary of certain identifiable trends and challenges to developing policies and actions the panel could take to support safe and efficient transport.

### 2.1.1 **What we know**

***Safety impacts of reduced State of Charge (SOC) on the probability of a lithium-ion cell or battery to go into thermal runaway***

a) Batteries shipped at a reduced SOC are known to be less prone to thermal runaway as demonstrated through testing.

b) The 30% SOC limit derived from testing of standard cells has been verified by multiple sources. It is recognized that the 30% limit might not be precise for all cell/battery designs; however, that limit is generally considered to be a practical safety limit to apply as a rule of general applicability.

c) The limit is applied based on data from testing at cell/battery level, therefore this measurement of the likelihood of a cell/battery to go into thermal runaway is independent of package or equipment transport configuration. See: Report: Summary of FAA Studies Related to the Hazards Produced by Lithium Cells in Thermal Runaway in Aircraft Cargo Compartments - www.fire.tc.faa.gov/pdf/TC-16-37.pdf

***Safety impacts of reduced SOC on the severity of reaction or consequence of thermal runaway***

a) Lower states of charge are well known for reducing the severity of a thermal runaway event. Test data indicates that severity from thermal runaway of commonly transported cells at 30% SOC or less is significantly reduced as compared to cells at higher SOCs, and in many cases, thermal runaway is not likely to propagate to other cells.

b) Package configurations, including density and proximity of cells impact the severity of an event. However, the ability to propagate to other cells is greatly reduced for cells under 30% SOC.

***Increasing Energy of lithium ion batteries***

a) Heat released during thermal runaway is impacted by the total energy storage capacity of a cell. Said another way, energy released during thermal runaway increases with increased stored energy.

b) U.S. Department of Energy information shows a trend of increasing energy density of lithium-ion batteries from 2008-2020. See FOTW #1234, April 18, 2022: Volumetric Energy Density of Lithium-ion Batteries Increased by More than Eight Times Between 2008 and 2020.

c) The practical impacts of increasing energy density are that batteries in thermal runaway release heat faster making it less likely that the heat generated can be dissipated to the surrounding environment leading to increased consequences of thermal runaway. See: Journal of Electrochemical Society, Investigating the Role of

energy Density in Thermal Runaway of Lithium-Ion Batteries with Accelerating Rate Calorimetry. Also see: DGP-WG/22-IP/1

***Increasing volume of shipments***

a) The panel reviewed information presented to DGP-WG/22 that represented U.S. Import-Export data for UN3480/UN3481/UN3090 transported by air from 2015-2021.

b) The figures indicate a continued increase in air transport of UN3481. Increased transport increases exposure to risk within the air transport system. See: DGP-WG/22-IP/14

***Aircraft cargo compartment capabilities***

a) Lithium batteries release hydrogen and other flammable gases at various stages of thermal runaway. Concentrations of these gases could exceed the ability of current fire suppression systems. See: DGP-WG/22-IP/9

b) Lithium batteries, if subjected to thermal runaway, have the potential to generate a pressure pulse within the cargo compartment. This pulse could potentially lead to the displacement of pressure relief panels, thus permitting the fire suppressant (halon) to escape into other compartments within the aircraft. This, in turn, could compromise the overall effectiveness/capabilities of the aircraft's fire suppression system. See: www.fire.tc.faa.gov/pdf/TC-16-37.pdf

2.1.2 **What we don't know**

2.1.2.1 Exact transport volumes and configurations of lithium batteries in any shipment and whether equipment adequately protects batteries from thermal runaway, contains the effects of a battery that has gone into thermal runaway or provides an additional means to initiate thermal runaway. There are infinite equipment designs incorporating batteries and package configurations containing equipment with batteries and defining a configuration that would support higher states of charge without propagation is difficult to predict. Despite extensive review of incident reports, causes of thermal events involving lithium batteries can only be attributed to general causes.

2.2 **INCIDENT REPORTS**

2.2.1 **What we know**

2.2.1.1 Incidents involving lithium ion batteries contained in or packed with equipment continue to occur within the air transport system and are not limited to one industry sector or geographic region. Most incidents were identified during storage incidental to transport, prior to loading and after unloading. Incidents also occurred during subsequent ground transport after the package was transported by air. Recorded incidents are relatively minimal in total, especially in comparison to the volume of shipments. The primary source of incident figures presented was from the UL managed voluntary system titled "Thermal Runaway Incident Program" or TRIP.

a) One relevant trend detected by the TRIP information is that incident reports for UN3480 have trended down since 2016 when ICAO implemented the 30% SOC limit

for packaged batteries, while incidents reports for UN3481 have trended up during that same time. See: DGP-WG/22-IP/10

b) An 11 April 2021 incident brought to the Panel's attention that occurred on the apron at Hong Kong International Airport involving a pallet containing cellular phones illustrates the consequences of a thermal runaway event involving consumer electronic devices containing a single installed lithium ion battery. See: DGP/28-IP/2

2.2.2 **What we don't know**

2.2.2.1 The cause of most lithium ion battery failures within the transportation system. Failure could arise from many factors, including non-compliance with manufacturing quality control, design testing, improper packaging, or rough handling. Recognizing there are incidents in the air transport system, there is not a specified number of incidents that would define an acceptable number of incidents. Further, there is not a measurement that considers an acceptable number of incidents when compared to a known mitigation measure to reduce risk.

## 2.3 ECONOMIC IMPACT AND MARKET FEASIBILITY

2.3.1 **What we know**

2.3.1.1 Implementation of a 30% SOC on packaged batteries for transport by cargo air did not stop the transport of packaged lithium ion batteries. The reduction of SOC for transport has become an accepted practice and experience indicates that the overall impact of implementing this safety mitigation measure is not as negative as might have been perceived. Import/export data indicate the use of lithium ion battery technology continues to expand. Anecdotal evidence also indicates that large well known lithium battery and equipment manufacturers ship products at a reduced state of charge. This implementation would appear to confirm that the technology exists to manage battery SOC. Although an approval reference was included for instances where air transport was necessary at higher than 30% SOC, very few approval requests have been submitted. Experience with packaged lithium ion batteries appears to show the ability to apply technology and process procedures to manage a specific SOC.

2.3.2 **What we don't know**

2.3.2.1 Some industry sectors already implement a process in their production line to control the state of charge prior to packaging and shipping. We do not currently have sufficient information to determine whether this practice is commonplace. Representatives from some sectors of industry indicated that implementation of a reduced SOC would be difficult or could cause extreme economic impact. It is unclear if this industry concern is related to safety, consumer marketing or simply a preference. No specific economic impact data has been provided that might indicate negative impacts on manufacturing processes, production times, or business practices.

## 2.4 REGULATORY COMPLIANCE LIABILITY FOR SHIPPER OTHER THAN THE OEM

2.4.1 **What we know**

2.4.1.1 A reduced SOC for batteries packed on their own and not for batteries packed with or contained in equipment was a conscious decision of the panel. Based on experience from implementation of a 30% SOC limit on packaged batteries, no significant hardship or inability to ship critical or time-

sensitive cargo has been verified. Comments from DGP/28 indicate a recognition that establishing a 30% SOC was routine for some battery manufacturers but not for others in the supply chain. Therefore, there's evidence to conclude that the technology and procedures exist for equipment manufacturers to manage battery SOC as well. Any change to a cell or battery by someone other than the original battery manufacturer could lead to additional risk to the air transport system. The shipper could verify the SOC limit through contractual conditions with their supplier, documentation, or physical verification, as appropriate. This verification may not be within the current business practice of some equipment distributors; however, experience indicates this verification is possible through adaptation of existing business practices. The current dangerous goods system is dependent on a level of trust in order to provide for efficient transport. Verification of an SOC requirement would therefore be consistent with how other dangerous goods transport provisions are verified once offered into the air transport system.

### 2.4.2 **What we don't know**

2.4.2.1 The industries producing and distributing electronic equipment containing or packed with lithium ion batteries is vast and ever expanding. We don't know every equipment configuration, application of use, market demand, customer performance demands, or inventory management practices. There is no known source to obtain that volume and detail of information. Rules of general applicability applied in the Technical Instructions largely reflect OEM practices. Lithium batteries and equipment offered for transport by secondary suppliers, non-OEM shippers, and end users introduce additional uncertainties including:

a) The extent of secondary markets that may modify a battery in some way;

b) If or how equipment distributors modify equipment containing lithium ion batteries;

c) How the safety/stability of lithium ion batteries change with normal use or whether certain types of use, misuse or other actions impact the safety of equipment and the batteries that would render them unacceptable for transport;

d) What additional risk these uncertainties introduce.

2.4.2.2 Further, it is challenging predict what additional types or applications of equipment might need to arrive at destination at a higher than 30% SOC, it might be appropriate to consider provisions to allow for the transport of equipment as needed where the risks are adequately managed.

## 2.5 **LOWER SOC COULD LEAD TO CELL DEGRADATION**

### 2.5.1 **What we know**

2.5.1.1 Previous discussions indicate that manufacturers regularly ship lithium ion battery powered products below 100% charge to maintain optimal product quality. Some expressed concern that batteries shipped at a 30% charge could self-discharge while in transport and storage. It has been stated in the past that over-discharged (below 0 volts) lithium batteries can lead to cell degradation and the potential thermal runaway during subsequent recharging. Battery over-discharge protection circuits and battery management systems prevent this occurrence by cutting off activity when the voltage falls below predetermined limits. One recent study involving cells and batteries of different form factors, cathode chemistries, and capacities show minimal to no loss of voltage after nine months of storage within a package. This indicates that transport and storage or relatively long periods do not create over-discharge

conditions. Further, the use of air transport typically implies an urgency for delivery. See: Journal of Electrochemical Society, Safety of Lithium-Ion Cells and Batteries at Different States-of-Charge

2.5.2 **What we don't know**

2.5.2.1 We have no data to indicate if there are current lithium ion battery compositions or chemistries that would pose a safety concern when shipped at a reduced state of charge.

## 2.6 PROVISIONS TO FACILITATE TRANSPORT OF CERTAIN LIFESAVING/LIFE-SUSTAINING MEDICAL DEVICES

2.6.1 **What we know**

2.6.1.1 Some members expressed sympathy during DGP/28 for ensuring any amendments to the Technical Instructions do not negatively impact the ability to expeditiously deliver critical medical devices where needed. Most of the examples provided relate to implantable medical devices. Providing an exception for implantable medical devices could be considered based on the small size of the batteries. Such an exception could be included easily as the term implantable is self-limiting and would not require a definition that might lead to application to unintended articles. The way by which the Technical Instructions characterize the hazard potential for lithium ion batteries is to force the battery into thermal runaway. Data indicates a battery's application has nothing to do with the likelihood or severity of thermal runway.

2.6.2 **What we don't know**

2.6.2.1 It has been difficult to obtain comprehensive and reliable data on the types of medical devices or the need for these devices to be received at destination at higher than 30% SOC. We have no data to indicate that a battery's intended use either positively or negatively impacts the safety of the battery during air transport – particularly a battery exposed to an external fire.

## 2.7 REVISITING ASSUMPTIONS FROM WHAT WE HAVE LEARNED

2.7.1 The Technical Instructions regulate packaged lithium batteries differently than lithium batteries packed with or contained in equipment. For example, packing instructions 967 for lithium ion batteries contained in equipment offer additional flexibility on the packaging permitted and do not include a state of charge limit as compared to packing instruction 965 for packaged lithium ion batteries. This flexibility is based largely on the assumption that equipment protects the batteries from mechanical damage, limits the quantities of spare cells and batteries when packed with equipment, and a requirement to protect equipment from accidental activation to mitigate identified hazards. Additional justification for regulating batteries packed with and contained in equipment differently than packaged batteries seems to be based on the following additional assumptions:

a) The net mass of lithium ion cells or batteries is small compared to the net mass of equipment;

b) The batteries contained in equipment are effectively separated from each other reducing the likelihood of thermal runaway propagation; and

c) The number of batteries per package is smaller compared to packaged battery shipments.

2.7.2 Recognizing these assumptions informed decisions of the Panel in the development of current requirements, the types of devices in use during that time were predominately notebook computers, cameras, and portable telephones. Batteries contained in those devices were primarily user replaceable, with hard outer casings containing cylindrical cells. More recently, the types of devices containing lithium batteries has evolved in include tablet computers, e-cigs, and outdoor power equipment. Batteries for consumer devices are now dominated by higher energy pouch cells with a flexible case permitting lighter, slimmer, more powerful devices. Also, the volume of shipments has increased dramatically, including large consignments of equipment containing batteries. This evolution warrants a review of the underlying assumptions to ensure they remain valid.

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## APPENDIX E

## LIST OF POTENTIAL ADDITIONAL REQUIREMENTS SCORED AGAINST THE MITIGATION ORDER OF PRECEDENCE AND RECOMMENDED ACTION

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
|---|---|---|---|---|
| CS 1.1 | Manufacturers do not conduct UN38.3 tests. | National authorities conduct inspections and surveillance on battery/equipment manufacturers to identify flawed assumptions in the battery testing and equipment environment and conditions that violate assumptions about usage conditions. | 3 | Add guidance to the new manual under development to support implementation of Annex 18 |
| | | Develop detailed requirements to identify acceptable design changes. | 2 | |
| | | Reduce the state of charge for rechargeable batteries. | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| CS 1.1A | Invalid UN 38.3 test results | Require competent authority approval of laboratories conducting UN38.3 testing. | 2 | 1. Submit informal paper to the Sixty-third session of the UN Sub-Committee (27 November to 06 December 2023) seeking support for a requirement in the UN Model Regulations<br>2. Submit formal proposal to Sixty-fourth session of the UN Sub-Committee if above supported |

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
|---|---|---|---|---|
| | | Reduce the state of charge for rechargeable batteries. | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| CS 1.2 | Manufacturers do not develop and adhere to a quality management system. | Develop detailed requirements for quality assessments including third-party verification. | 2 | 1. Submit informal paper to the Sixty-third session of the UN Sub-Committee (27 November to 06 December 2023) seeking support for the development of detailed requirements for inclusion in the UN Model Regulations<br>2. Submit formal proposal to Sixty-fourth session of the UN Sub-Committee if above supported |
| | | Develop safety features for battery powered equipment | 4 | No action proposed. Requiring manufacturing requirements through transport regulations is complicated. |
| | | Reduce the state of charge for rechargeable batteries. | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| CS 1.3 | Shipper does not utilize lithium battery test summary information to make a classification decision. | Require shippers to produce lithium battery test summaries as a condition for carriage | 2 | No action recommended. Considered problematic and the effectiveness of this would be low |

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
|---|---|---|---|---|
| CS 2.1 | Shipper does not protect the battery from short circuits or damage prior to placement of the battery in the package with equipment. | Increase awareness of shipping and transport requirements | 2 | Add safety promotion guidance in the new manual under development to support implementation of Annex 18 |
| | | Require training for all shippers | 2 | No action proposed. Training is already required for batteries and equipment in accordance with Section I of the lithium battery packing instructions. It is considered infeasible to require it with those shipped in accordance with Section II due to the potential for every person in the world to be a shipper of these. |
| | | Reduce the state of charge for rechargeable batteries | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| | | Design equipment to protect installed batteries | 4 | No action proposed. Requiring manufacturing requirements through transport regulations is complicated. |
| | | Require more robust packaging | 3 | Consider adding requirement for packages to be capable of withstanding a 3 m stack test |
| CS 2.2 | Shipper/packer does not secure equipment within the outer packaging when offering for transport | Increase awareness of shipping and transport requirements | 2 | Add safety promotion guidance in the new manual under development to support implementation of Annex 18 |
| | | Require training for all shippers | 2 | No action proposed. Training is already required for batteries and equipment in accordance with Section I of the lithium battery |

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
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| | | | | packing instructions. It is considered infeasible to require it with those shipped in accordance with Section II due to the potential for every person in the world to be a shipper of these. |
| | | Reduce the state of charge for rechargeable batteries | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| | | Design equipment to protect installed batteries | 4 | No action proposed. Requiring manufacturing requirements through transport regulations is complicated. |
| CS 3.1 | Shipper/ packer selects a package of insufficient strength leading to damage of the contents during handling. | Increase awareness of shipping and transport requirements | 2 | Add safety promotion guidance in the new manual under development to support implementation of Annex 18 |
| | | Require training for all shippers | 2 | No action proposed. Training is already required for batteries and equipment in accordance with Section I of the lithium battery packing instructions. It is considered infeasible to require it with those shipped in accordance with Section II due to the potential for every person in the world to be a shipper of these. |
| | | Reduce the state of charge for rechargeable batteries | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
|---|---|---|---|---|
| | | Design equipment to protect installed batteries | 4 | No action proposed. Requiring manufacturing requirements through transport regulations is complicated. |
| | | Require more robust packaging | 3 | Consider adding requirement for packages to be capable of withstanding a 3 m stack test |
| CS 3.2 | Ground handling service provider damages packages during handling | Require quarantine or inspection of all packages subject to suspected damage | 3 | Add a recommendation for operators to establish procedures to follow when damage is suspected or after dropping packages with lithium batteries. Potentially for multimodal as well. |
| | | Reduce the state of charge for rechargeable batteries | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| | | Design equipment to protect installed batteries | 4 | No action proposed. Requiring manufacturing requirements through transport regulations is complicated. |
| | | Review training and procedures for package handlers | 2 | If handling procedures are added to the Technical Instructions, training would naturally follow. |
| | | Require more robust packaging | 3 | Consider adding requirement for packages to be capable of withstanding a 3 m stack test |
| CS 4.1 | Shipper does not apply appropriate marks, labels, or indicate the presence of lithium batteries in a consignment. | Eliminate provisions that allow consignments to be transported without identifying marks and documentation | 3 | No action proposed. |
| | | Require training for all shippers | 2 | No action proposed. Training is already required for batteries and equipment in accordance with Section I of the lithium battery |

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
|---|---|---|---|---|
| | | | | packing instructions. It is considered infeasible to require it with those shipped in accordance with Section II due to the potential for every person in the world to be a shipper of these. |
| | | Reduce the state of charge for rechargeable batteries | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>3. See justification below |
| | | Design equipment to protect installed batteries | 4 | No action proposed. Requiring manufacturing requirements through transport regulations is complicated. |
| | | Require more robust packaging | 3 | Consider adding requirement for packages to be capable of withstanding a 3 m stack test |
| | | Require shipper to sign a declaration that package or consignment does not contain dangerous goods | 2 | 1. Require shippers to sign a declaration that package does not contain dangerous goods in an appropriate ICAO document (e.g. Annex 6 — *Operation of Aircraft* or Annex 9 — *Facilitation*)<br>2. Require that operators not accept packages without signed declaration |
| 4.2 | Operator accepts a consolidation of multiple consignments of lithium batteries contained in equipment in a mail sack without marks, labels, | Eliminate provisions that allow consignments to be transported without identifying marks and documentation | 3 | No action proposed. I can't remember justification for no action |
| | | Require training for all mailers | 2 | No action proposed. It is considered infeasible to require it with those shipped in accordance with Section |

| Causal scenario ID | Causal scenario description | Recommended mitigation description | Mitigation effectiveness score | DGP-WG/ESD recommendation |
|---|---|---|---|---|
| | and declaration. | | | II due to the potential for every person in the world to be a shipper of these. |
| | | Reduce the state of charge for rechargeable batteries | 4 | 1. Mandatory requirement for packed with equipment<br>2. Recommendation for contained in equipment<br>See justification below |
| | | Institute requirements for mailers to indicate the presence of electronic equipment or items containing batteries or attest to the absence of electronic equipment containing lithium batteries. | 2 | 3. Require mailers to sign a declaration that package does not contain dangerous goods.<br>4. Require postal operators to not accept packages without signed declaration |

**— END —**