



**DANGEROUS GOODS PANEL (DGP)  
WORKING GROUP MEETING (DGP-WG/17)**

**Montreal, 24 to 28 April 2017**

**Agenda Item 5: Specific work items identified by the Air Navigation Commission:**

**5.3: Mitigating risks posed by the carriage of lithium batteries by air (ANC job card  
DGP.003.01)**

**PRESENTATION ON ENSURING SAFE TRANSPORT OF LITHIUM BATTERIES BY AIR**

(Presented by a Representative of the Medical Device Battery Transport Council)



# SAFE2FLY PROGRAM

## ENSURING SAFE TRANSPORT OF LITHIUM BATTERIES BY AIR

PRESENTED BY:  
STEPHANE ROSSETTI  
*SR MANAGER, SUPPLY CHAIN/ LOGISTICS*  
MEDTRONIC

26-APR-2017 / ICAO MONTREAL



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# ICAO DGP WG MEETING

## AGENDA



- Company Presentation
- Safe2Fly Program
- Amend exemption provision
  - Applying to standalone batteries on passenger aircraft in the interest of public health
- Packaging Testing
  - Performed on cells/ batteries contained in medical devices

# PRESENTATION

MEDICAL DEVICE BATTERY TRANSPORT COUNCIL

MEDTRONIC

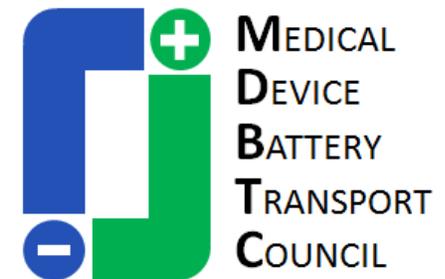
# MEDICAL DEVICE BATTERY TRANSPORT COUNCIL PRESENTATION

## SAFE2FLY PROGRAM - INDUSTRY PARTNERSHIP

The Medical Devices Battery Transport Council (**MDBTC**) is comprised of companies that manufacture and distribute life-saving and enhancing medical devices and the batteries that power them.

The MDBTC works with regulators and safety advocates to identify risk reduction opportunities that are less likely to impede aircraft transport to ensure patients receive vital life-saving and enhancing devices and spare batteries in a timely manner.

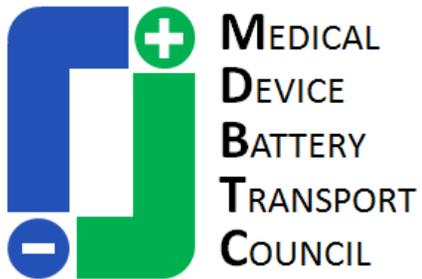
Learn more at [MDBTC.org](http://MDBTC.org)



**Committed to working with all parties to find/ implement reasonable solutions that enhance air transportation safety**

# MEDICAL DEVICE BATTERY TRANSPORT COUNCIL PRESENTATION

## COMPANY MEMBERS



**All Dedicated To Patient Safety**

## MEDTRONIC PRESENTATION

### SAFE2FLY PROGRAM - INDUSTRY PARTNERSHIP

**Medtronic**

Further, Together

As a global leader in medical technology, services and solutions, Medtronic improves the lives and health of millions of people each year.

We use our deep clinical, therapeutic and economic expertise to address the complex challenges faced by healthcare systems today.

Let's take healthcare Further, Together.

Learn more at [Medtronic.com](https://www.Medtronic.com)

***Alleviate Pain, Restore Health, Extend Life***

# SAFE2FLY PROGRAM

VERIFICATION / CERTIFICATION

## VERIFICATION PROGRAM

### SAFE2FLY PROGRAM - INDUSTRY PARTNERSHIP



**Underwriters  
Laboratories**



**American Airlines** 



Working collaboratively to  
develop a voluntary  
certification program of  
known shippers and products

# SAFE2FLY PROGRAM

## HIGH LEVEL OVERVIEW



### PROGRAM BASICS

- VOLUNTARY Program
- NOT to replace any current regulations requirements
  - Imposes CONTROLS to the current regulations
- ALL shipments to comply with all current AIR regulations requirements
- Future integration of:
  - G27 Packaging Performance Standards
  - Lithium Batteries Classification Process
- Valid for **Stand-alone** cells/batteries and **Contained or Packed** with equipment
- Similar as U.S. Export Administration Regulations (EAR)
  - U.S. Department of Commerce to control exports (ACE)

# VERIFICATION PROGRAM

## HIGH LEVEL PRINCIPLES

### GUIDED BY 3 CONTROLS

#### 1-Shipper

- 3<sup>rd</sup> Party Audit
  - Regulatory Compliance
  - DG Program
  - Training
  - Packaging/Marking/Labeling Review
  - Readiness/Fitness

**VERIFIED/KNOWN SHIPPER**

#### 2-Product

- 3<sup>rd</sup> Party Audit
  - UN38.3 Report
  - Product Classification
  - UN#/PSN/ELC/W-h/30SOC/weight/PSDS
  - Manufacturing Controls
  - Quality Mgmt System

**VERIFIED/KNOWN PRODUCT**

#### 3-Shipment

- 3<sup>rd</sup> Party Verification
  - Known Shipper
  - Known Product
  - Known Carrier

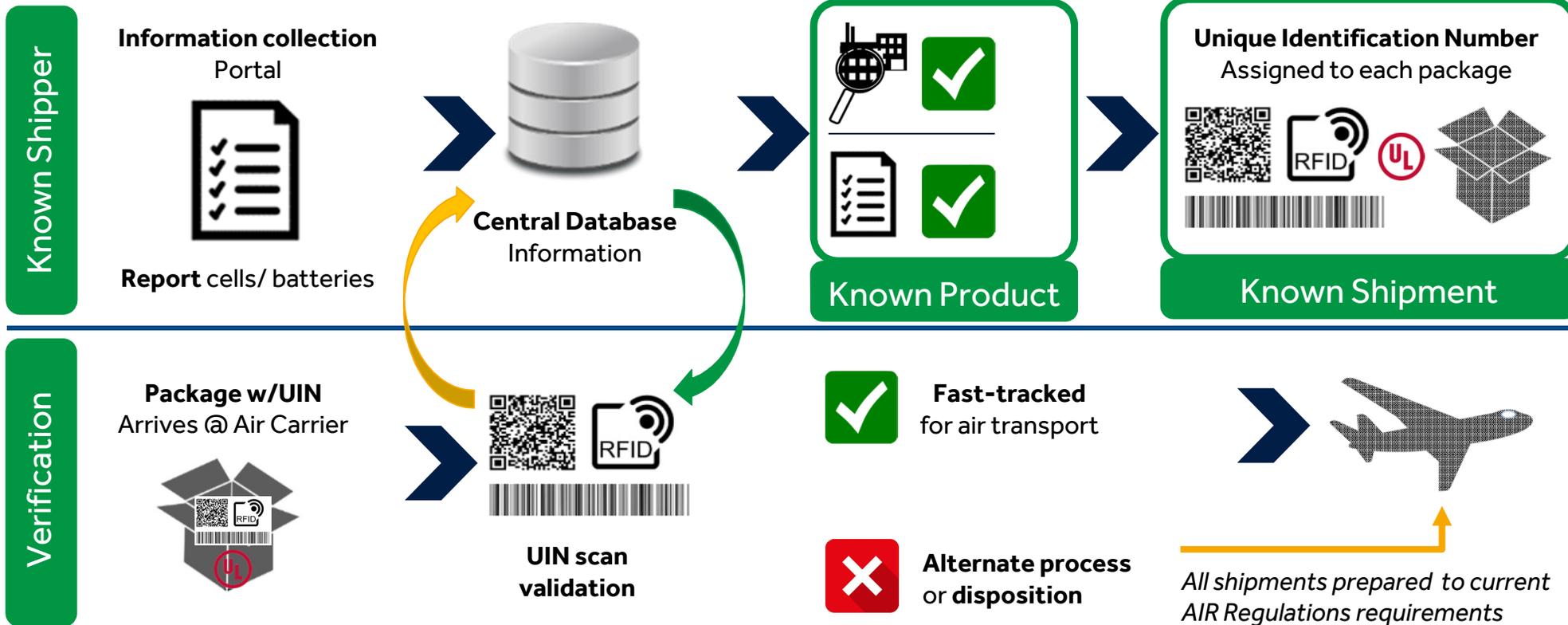
**VERIFIED/KNOWN SHIPMENT**

**Central Database Information**

# VERIFICATION PROGRAM

## HIGH LEVEL PRINCIPLES

### SHIPPING PROCESS CONCEPT



# VERIFICATION PROGRAM

## SAFE2FLY INDUSTRY PARTNERSHIP

### Take-Away

## Combining Aviation Safety and Battery Science



Adobe Acrobat  
Document



**Captain Bob Brown**  
IPA Safety Task Force  
bbrown@ipapilot.org



## Ensuring Batteries are “Safe2Fly”

### Combining Aviation Safety and Battery Science

The Independent Pilots Association (IPA) is aggressively promoting safer methods for transporting batteries on aircraft. Our role has resulted in developing significant risk mitigation strategies. The most important initiative under development is called “Safe2Fly” which advocates a comprehensive end-to-end program to address gaps in the battery transportation supply chain. Developing this program involved combining our knowledge of aviation safety and risk with Underwriters Laboratories (UL) understanding of battery science and product safety. The purpose of this article is to highlight UL as an independent Third party that is actively involved in battery safety, describe the practical workings of the Safe2Fly program and provide a series of questions and answers related to developing such a program.

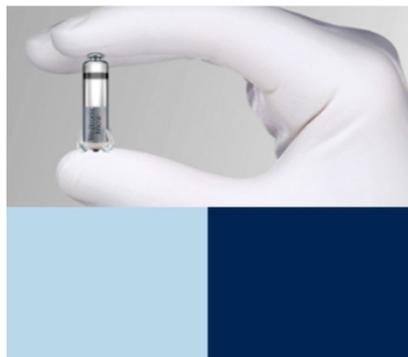
#### Safety Standards and UL

Innovation brings the promise to better our lives, but with it often come new risks and complexities that can threaten product safety, security and sustainability. UL applies science to help solve these complex challenges and makes the safe adoption of innovation possible. The mission of UL is to enable safe, secure, sustainable working and living environments for all. For more than 120 years, UL’s science and expertise in the development of safety standards has helped innovation fulfill its’ promise, so that products once deemed dangerous can be made safer. A recent example comes from examining the hoverboard debacle. The hoverboard literally became the “hottest gift” in 2015 as the number of house fires surged. This led to a ban on transportation by U.S. airlines and involvement from the U.S. Consumer Products Safety Commission.

# EXEMPTION PROVISIONS AMENDMENT

FOR MEDICAL DEVICES

## EXEMPTION PROVISION AMENDMENTS FOR MEDICAL DEVICES – WHY IS THIS NEEDED?



**MEET MICRA.**  
MINIATURIZED.  
SOPHISTICATED.  
COMPLETE.

The revolutionary new leadless pacemaker is implanted inside the heart.

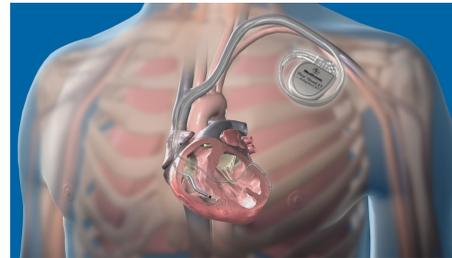
[LEARN MORE](#)

- Amend exemption provision applying to bulk batteries on **passenger aircraft** in the interest of public health
- Exemptions are difficult to acquire
- Modify process from “Exemption” to “Approval”
  - **Exemption** requires State of Origin, Overflight, Operator and State of Destination
  - **Approval** requires only State of Origin
- Proposing change to an **approval provision** similar to the approval for the 30% State of Charge provision based on A331 of the Technical Instructions

**Every 31 seconds,  
a Medtronic device using a lithium battery is implanted**

# EXEMPTION PROVISION AMENDMENTS FOR MEDICAL DEVICES

- Class II and Class III (according to [FDA definition](#))
  - **In the Body** (Implantable)
  - **On the Body** (Pumps, ventilators, hearing aid)
  - **For the Body** (External equipment)
- For life-saving and life-enhancing devices
  - Shipping a few medical device batteries on PAX does not pose a serious risk but is needed for public health
- Only when NOT serviced or timely serviced by CAO
- ISO13485 for medical devices



**Approved by the FDA to be implanted in human body for "7" years**  
**Safe for AIR transport for "7" hours**

# PACKAGING TESTING

FOR MEDICAL DEVICES

## PACKAGING TESTING

### HIGHEST SAFETY STANDARDS



30 cells; 1.11 W/h [34 W/h]



[Video]



180 cells; 9.62 W/h [1,700 W/h]

- Testing performed on cells contained in implantable medical devices
- Individual Pockets; Preventing shifting
- No fire propagation from cell to cell
- Short-circuit protection
- Qualified & Validated Inner-Trays
  - Medical device packaging has to be approved by agencies such as the FDA
  - Approval process can take up to one year
- Low Energy/Density (1/50 Ratio)
- Important factors to transportation safety

# SUMMARY

## SUMMARY

### SAFE2FLY PROGRAM

<b>Industry Partnership</b>	<b>3<sup>rd</sup> Party Verification</b>	<b>Controls/ Validation</b>	<b>Exemption Provisions</b>	<b>ASKS</b>
<ul style="list-style-type: none"><li>▪ Underwriters Laboratories</li><li>▪ Independent Pilots Association</li><li>▪ American Airlines</li><li>▪ Medical Device Battery Transport Council</li></ul>	<ul style="list-style-type: none"><li>▪ Shipper</li><li>▪ Product</li><li>▪ Shipment</li></ul>	<ul style="list-style-type: none"><li>▪ Known Shipper</li><li>▪ Known Product</li><li>▪ Known Shipment</li></ul>	<ul style="list-style-type: none"><li>▪ Amend exemption provision applying to standalone batteries on passenger aircraft in the interest of public health</li></ul>	<ul style="list-style-type: none"><li>▪ Provide comments on Program safety</li><li>▪ Provide an update during the DGP meeting in Nov, 2017</li><li>▪ Participation at future DGP meetings where lithium batteries are discussed</li></ul>

***Quality Is Not Expensive, It Is Priceless!***

**Q&A**

**THANK YOU**

**Medtronic**  
Further, Together