Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods 3 October 2016

Fiftieth session
Geneva, 28 November-6 December 2016
Item 11 of the provisional agenda
Other business

Application for consultative status

(Medical Devices Battery Transport Council) (MDBTC)

Note by the secretariat

1. The secretariat has received the application reproduced hereafter.

2. In accordance with established practice, non-governmental organizations (NGOs) that are not in consultative status with the Economic and Social Council may request to be consulted by the Sub-Committee when matters within their field of competence are being discussed. They are then requested to provide the secretariat with the information required in paragraph 44 of the Economic and Social Council resolution 1996/31 (https://www.unodc.org/documents/congress//Participation/NGO_Annex_website.pdf) and other relevant information (csonetorg/?menu=83)

3. When considering applications from NGOs, the Sub-Committee should taken account of the principles contained in parts I and II of the Economic and Social Council resolution 1996/31.

4. MDBTC has been informed by the secretariat that one of the requirement for obtaining consultative statut with the Economic and Social Council is that the NGO must have been in existence (officially registered) for at least two years at the date of application. Since this requirement is not met, and since the MDBTC application is not an application for consultative status with the Economic and Social Council itself, it is up to the Sub-Committee to decide whether this requirement may be required or not.

MEDICAL
DEVICE
BATTERY
TRANSPORT
COUNCIL

April 15, 2016

Olivier Kervella
Chief, Dangerous Goods and Special Cargoes Section
Secretariat, Economic Commission for Europe
Inland Transport Committee Transport of Dangerous Goods
Office: 418
Palais des Nations,
CH - 1211 Geneva 10
Switzerland

Dear Mr. Kervella,

The Medical Device Battery Transport Council (MDBTC) is a coalition of medical device manufacturers that advocate for responsible regulations for the transportation of medical devices and the lithium batteries that power them. The MDBTC works toward acheiving its objectives through the process of 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 MDBTC requests observer status to the United Nations Transport of Dangerous Goods Sub-Committee meetings. The MDBTC believes that it can provide positive contributions to the Sub-Committee's work program. Please find attached information and application form relative to the MDBTC to support the request for observer status which will enable the MDBTC to contribute to the work of the United Nations Transport of Dangerous Goods Sub-Committee meetings.

We believe the enclosed application should be adequate for consideration, however, if it can be arranged, with your assistance, a member of MDBTC would like to attend the next session to respond to any questions that may arise. If you do have any questions concerning our application, please do not hesitate to contact Bob Richard, Executive Director, MDBTC at +1-773-540-0837 or brichard@labelmaster.com.

Yours faithfully,

S N LaPierre

Steven LaPierre, Chairman MDBTC

Application Form for Observer Status

1. Name of Organization
Medical Device Battery Transport Council (MDBTC)

2. Purpose of the Organization
The MDBTC is comprised of global companies that manufacture and distribute life-saving medical devices and the lithium batteries that power them. The purpose of this Council is to work with regulators, standards bodies (e.g. ISO, IEC, UL, SAE, etc.) and safety advocates to identify risk reduction opportunities to enhance transport safety and that are less likely to impede transport and the ability for patients to receive vital life-saving and enhancing devices in a timely manner. The MDBTC was formed in response to recently implemented regulations and consequential restrictions imposed by individual airlines that have negatively impacted the ability of MDBTC member companies to ship their life-saving products to patients. The MDBTC is a strong advocate for the safe transport of lithium batteries and therefore is not opposed to new regulations that minimize risk during transportation.

The council represents companies that manufacture both implantable and portable life-saving medical devices such as electronic pacemakers, automated external defibrillators, neurological stimulators, and the lithium cells and batteries that power them.

There are currently 6 member companies. Numerous member company representatives participate in bimonthly meetings. Member companies have facilities in numerous countries worldwide. For instance Medtronic does business in 120 countries worldwide and has facilities in the following locations: http://www.medtronic.com/intl/comm.html. Boston Scientific has approximately 23,000 employees around the globe, including sales forces in 40 countries: http://www.bostonscientific.com/en-US/about-us/locations.html.

If needed the worldwide presence for each member company can be provided.

3. Contact Information
Medical Device Battery Transport Council

Bob Richard
MDBTC Executive Director
E-mail: brichard@labelmaster.com
Tel: +1-773-540-0837

Main office location:

MDBTC
10036 Lake Occoquan Drive
Manassas, Virginia, USA
20111

4. Affiliated Organizations
The Medical Device Battery Transport Council (MDBTC) is a coalition of the leading multinational manufacturers of medical devices and the lithium batteries that power them. The mission of the MDBTC is to advocate for responsible regulations for the transportation of lithium batteries used for medical devices. By working directly with regulators and other important stakeholders, the MDBTC hopes to build a consensus that leads toward the development of regulations that enhance transportation safety without disrupting critical medical device supply chains. This Council is made up of member companies that operate in numerous countries worldwide and membership is open to

any medical device or battery manufacturer that strives to enhance the safety of their products in transportation.

The operation of this Council is directed by its Bylaws and guided by operating policies and procedures adopted by Council member companies.

The MDBTC works closely with other medical device organizations including ;

-Medical Device Manufacturers Association (MDMA) ;
-Advanced Medical Technology Association (AVAMED - formerly the Health Industry Manufacturers Association) ;
-Association for the Advancement of Medical Instrumentation (AAMI) ; and
- National Electrical Manufacturers Association (NEMA).

5. Activities of the Organization

The Medical Devices Battery Transport Council (MDBTC) was formed to promote the safe transport of lithium batteries and battery-powered medical devices. The MDBTC agrees with regulators that safety of both passengers and crew is of the utmost importance, and to that point, is supportive of rules that enhance safety for all parties involved in air transport. Further, the MDBTC shares a common bond with regulatory groups in that each member company has a strong interest in seeing that their lithium battery shipments arrive at the destination safely. This council aims to work with regulators to identify risk reduction opportunities while also mitigating the impacts of overly burdensome regulations that have an adverse effect on the efficient transportation of life-saving products worldwide.

Members of the MDBTC are well-established companies with international reach, each with decades of experience in the medical industry. The council represents companies that manufacture both implantable and portable life-saving medical devices such as electronic pacemakers, automated external defibrillators, neurological stimulators, and the lithium cells and batteries that power them. Together, the companies that comprise this council account for a significant share of the global market of these products. Each council member has a long-standing hazardous materials compliance program and a proven safety track record.

The MDBTC was formed in response to recently implemented regulations and consequential restrictions imposed by individual airlines that have negatively impacted the ability of MDBTC member companies to ship their life-saving products to patients. The MDBTC is a strong advocate for the safe transport of lithium batteries and therefore is <u>not</u> opposed to new regulations that minimize risk during air transportation. However, the council requests that regulatory decision-makers focus on addressing the root causes of incidents and consider the impacts to lithium battery supply chains.

6. Confirmation of Interest in the goals and objectives

MDBTC members have participated in relevant domestic, regional and international regulatory and standards development meeting as members of other organizations or individual companies. Being approved for observer status at the UN TDG SC would allow members to share information and contribute to regulatory developments that take into account the impacts to public health and medical device supply chains. Members can share best practices that contribute to safety but are not currently addressed in regulations. Members are interested in proposing additional lithium battery entries and requirements to account for medical device technology. MDBTC member companies have made valuable contributions to improving the safe transport of dangerous goods particularly in relation to going above and beyond current safety requirements for the transportation of lithium cells and batteries.

Many of our members are Certified Dangerous Goods Professionals as well as holding other certifications related to dangerous goods transport (DGSA). The work currently being undertaken by the MDBTC is consistent with the United Nations' ultimate goal of enhancing the safe transport of dangerous goods. The MDBTC works not only to promote responsible regulations for shipments of medical device batteries, but also to educate regulators and interested parties on the enhanced safety of the batteries manufactured by member companies. MDBTC member companies exceed current safety standards with respect to battery desgn, manufacturing processes, material supply chain controls, packaging, design type and production lot testing, and quality management systems. Council members are proud of the high standards demanded of their products, and as a result, have experience few, if any, instances in which a lithium battery in one of its products was associated with a fire or other hazard that could pose a risk in transportation.

7. Copies of the financial statements

The MDBTC is a not for profit organization. The activities of the MDBTC are fully funded by annual contributions from the member companies. A copy of the MDBTC financial statement is attached.

8. Governing Body of the Organization

The operation of the MDBTC is managed by representatives from the member companies. The current representative board consists of :

Steven LaPierre, Boston Scientific - Chairman

David Collings, Philips Healthcare – Board Member

Bill Withrow, Baxter Healthcare - Board Member

Kathleen O'Shei, Greatbatch - Board Member

Trevor Gunn, Medtronic - Board Member

Bob Richard, Labelmaster Services – Executive Director, Treasurer

Michael Pagel, Labelmaster Services – Secretary

9. **Constitution and/or by-laws of the organization**

The MDBTC's By-Laws are attached.

9. Publications of relevance to the work of the Sub-Committee

The MDBTC has published a White Paper that may be of interest to the TDG Sub-Committee. A copy will be provided with our submission. Members participate on standards bodies such as ISO and IEC to contribute to the publication of consensus standards. The MDBTC has worked with other members of the TDG-Sub-Committee to draft and provide comments on papers and is planning to submit proposals to the Sub-Committee related to the transport of medical devices and the batteries that power them if the organization's application for membership is accepted. MDBTC members have participated and developed proposals considered by the UN Lithium Battery Working Group. MDBTC's Executive Director has written numerous media articles addressing the importance of being able to ship medical devices and the batteries that power them in commerce and how recently adopted ICAO regulations impact supply chains. MDBTC members have conducted public seminars to educate shippers of lithium batteries and medical devices.

Summary of recent activities :

In the face of the current regulatory climate, the MDBTC used 2015 to gain industry recognition, communicate our goals, share best practices, respond to regulatory proposals, participate in regulatory meetings, and plan our direct proposal to regulatory bodies. A selection of this Council's recent achievements includes:

Development of the MDBTC mission statement, by-laws and documents describing the organizational objectives.
Conducted member conference calls and distributed meeting minutes.
Participated in regulatory and public meetings.
Invited regulatory and airline experts on conference calls to share their views and educate them on the MDBTC mission and objectives and to strategize on regulation development.
Convened technical working group meetings to strategize and document medical device battery best practices and shipping processes.
Participated in an IFALAPA meeting in Madrid, Spain to educate pilots on the safety measures associated with medical device batteries;
In-person meetings to share the MDBTC's goals and concerns with influential regulators, including:
U.S. Ambassador to ICAO, Michael Lawson
ICAO Air Navigation Commissioner, Bill Voss
Staff of the U.S. Department of Transportation (DOT) Office of the Secretary including DOT's Chief Council, Kathryn B. Thomson
Staff of PHMSA's Standards and Rulemaking Division including Duane Pfund
Republican & Democratic Congressional representatives involved in transportation committees – developed amendments to the FAA Reauthorization Bill
Presented MDBTC mission and objectives at:
Delivered a presentation to the IATA Dangerous Goods Board to educate airlines on the safety measures associated with medical device batteries and to provide comments on ICAO DGP proposals;
Delivered a presentation at the Air Line Pilot's Association's (APLA) Air Cargo Symposium
Hosted Tour of Medtronic (MECC) Battery Manufacturing Site with FedEx, UPS and IFALPA Representatives.
Met with packaging manufacturers to explore novel packaging solutions for lithium battery shipments.
Prepared United Nations (UN) Observer Status Application for the Council's direct participation at regulatory meetings.
Drafted a UN Paper to propose a new Packing Instruction for lithium batteries for medical devices.
Promoted the mission and objectives of the MDBTC through media news articles and assisted with informing regulators and the public about potential downstream consequences related to patient health and well-being.
Provided members with timely information regarding regulatory proposals and meetings resulting in potential impacts to member companies.
Kept member companies informed of any changes to requirements concerning:
Damaged/defective lithium battery transportation;
UN Manual of Tests and Criteria 38.3 requirements;
Individual airline restrictions or embargoes;
Lithium battery waste, storage, and disposal; and
Emergency response procedures.
Participated in the Society of Aeronautical Engineers (SAE) G-27 Lithium Battery Performance Standard Committtee ;
Participated in the UN Lithium Battery Working Group in Bordeaux, France.
Worked with US Senate staff to draft amendments to the FAA Reathorization Bill.

MDBTC Financial Report in US Dollars

2015- 2016

	Actual 2015	Budget 2016
Revenues		
Membership Contributions	59,876	82,500
Workshops/Conferences		0
Certification Fees		0
Other		0
Total Revenues	59,876	82,500
Direct Expenses		
Labor and Expense Billing	59,876	62,000
Meetings/Conference		3,000
Supplies/Printing/Legal		12,000
Travel		4,500
Bank/PayPal/Tax Fees		1,000
Total Direct Expenses	59,876	82,500
Sub Total		
Overhead		2,000
Net Profit/(Loss)	0	0

These are unaudited financial summaries. Some expenses are estimates based on good faith best knowledge.

MEDICAL DEVICE BATTERY TRANSPORT COUNCIL

MEDICAL DEVICE BATTERY TRANSPORT COUNCIL

Executive Summary

The mission of the Medical Device Battery Transport Council (MDBTC) is to advocate for responsible regulations for the transportation of medical devices and the lithium cells and batteries that power them. Due to the timely nature in which medical devices are needed, this council is focused on ensuring that lithium cells and batteries can be transported safely by passenger and cargo aircraft. By working directly with regulators and other stakeholders, the MDBTC hopes to build a consensus that leads toward the development of regulations that enhance transportation safety without disrupting critical medical device supply chains.

The MDBTC understands the necessity of responsible transportation regulations yet remains concerned that regulators are overlooking the impact their decisions are having on the global health community. With this document, the MDBTC intends to show that the batteries they use in their medical devices meet strict safety standards – far beyond what is required by dangerous goods transportation regulations. MDBTC member companies go above and beyond current regulatory requirements with respect to battery design, manufacturing processes, material supply chain controls and qualifications, packaging, design type and production lot testing, and quality management systems. As a result of these enhanced safety measures, MDBTC member companies are aware of few, if any, instances in which a lithium battery in one of its products was associated with a fire or other hazard that has or could pose a risk in transport**.**

The majority of lithium cell or battery incidents involved products that were not in compliance with current regulations. Unscrupulous shippers continue to offer lithium cells and batteries for transport illegally and without being held accountable for their actions. Rather than implementing additional restrictions, the MDBTC believes that aggressive enforcement of current regulations is needed. The International Civil Aviation Organization and governments worldwide need to increase their focus on ensuring appropriate jurisdiction, oversight and behavior-changing actions are implemented to hold manufacturers and shippers accountable for their actions to reduce the risk that sub-standard products pose to the public and aviation safety.

Finally, the MDBTC intends to make their case with the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods, the International Civil Aviation Organization (ICAO), and other regulatory bodies in hopes of moving forward on regulations that promote safe transport of medical devices and the lithium batteries that power them. MDBTC members will be active in working with regulators on arriving at specific mitigation strategies designed to enhance safety without unnecessarily disrupting lithium battery supply chains and the ability for patients to receive the medical devices and replacement batteries they need.

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Mission & Objectives:

The Medical Devices Battery Transport Council (MDBTC) was formed to promote the safe transport of lithium batteries and battery-powered medical devices. The MDBTC agrees with regulators that safety of both passengers and crew is of the utmost importance, and to that point, is supportive of rules that enhance safety for all parties involved in air transport. Further, the MDBTC shares a common bond with regulatory groups in that each member company has a strong interest in seeing that their lithium battery shipments arrive at the destination safely. This council aims to work with regulators to identify risk reduction opportunities while also mitigating the impacts of overly burdensome regulations that have an adverse effect on the efficient transportation of life-saving products worldwide.

Members of the MDBTC are well-established companies, each with decades of experience in the medical industry. The council represents companies that manufacture both implantable and portable life-saving medical devices such as electronic pacemakers, automated external defibrillators, neurological stimulators, and the lithium cells and batteries that power them. Together, the companies that comprise this council account for a significant share of the global market of these products. Each council member has a long-standing hazardous materials compliance program and a proven safety track record.

The MDBTC was formed in response to recently implemented regulations and consequential restrictions imposed by individual airlines that have negatively impacted the ability of MDBTC member companies to ship their life-saving products to patients. The MDBTC is a strong advocate for the safe transport of lithium batteries and therefore is <u>not</u> opposed to new regulations that minimize risk during air transportation. However, the council requests that regulatory decision-makers focus on addressing the root causes of incidents and consider the impacts to lithium battery supply chains. Rather than enhancing safety, this council fears that the implementation of overly complex regulations will result in unintended consequences including complications in employee training and an increased likelihood of outright non-compliance by shippers who are already not committed to safety. It is for these reasons the MDBTC supports the development of responsible, risk-based regulations in combination with aggressive enforcement against non-compliant shippers.

Impacts on Society & Public Health

Efficient supply chains are vital to the timely transportation of life-saving and life-enhancing products manufactured and distributed by MDBTC member companies. When making decisions concerning lithium battery supply chains, regulators must also take into account the implications of their decisions on public health and quality of life *outside* of the aviation community. The MDBTC understands the necessity of responsible transportation regulations yet remains concerned that regulators are overlooking the impact their decisions are having on the global health community. A regulation reducing a target risk for one area may increase risks in other areas, ultimately resulting in greater loss of life and other adverse consequences. Safety agencies must be careful to avoid overlooking countervailing risks and examine potential risk trade-offs.

Currently, there is significant attention focused on the transport of lithium batteries, particularly by air. Recent actions by ICAO prompted by the Federal Aviation Administration, the International Federation of Airline Pilots (IFALPA), and others, have resulted in additional restrictions including prohibiting lithium metal batteries aboard passenger aircraft. This prohibition became effective from January 1, 2015

based on the 2015-2016 ICAO Technical Instructions on the Safe Transport of Dangerous Goods by Air (ICAO TI).

The ban on lithium batteries aboard passenger aircraft is already having negative ripple effects throughout the industry. A number of airlines including Air France, Emirates and Qantas have implemented variations imposing restrictions for transporting lithium metal batteries on cargo aircraft as well. Furthermore, some airlines have adopted carrier variations that prohibit the transportation of all standalone lithium batteries – both ion and metal – aboard passenger and cargo aircraft. The number of air carriers that have imposed these types of restrictions is significant and increasing every day. This has significantly impacted the supply chains of medical device manufacturers and has implications to global health care and patient well-being. For example, there is currently no airline (cargo or passenger) that will carry lithium metal cells or batteries (UN3090) into New Zealand. Thousands of life-saving medical devices are deployed in New Zealand, and now it takes weeks to supply batteries for these devices.

The ICAO Dangerous Goods Panel (DGP), which is responsible for promulgating the ICAO Technical Instructions on the Safe Transport of Dangerous Goods (ICAO TI), has indicated that they are considering imposing additional restrictions on lithium battery shipments including those transported aboard cargo aircraft, packaged in overpacks and those packed with or installed in equipment. ICAO hosted an International Multidisciplinary Lithium Battery Transport Coordination Meeting from 9-11 September 2014 that developed 14 recommendations including imposing further restrictions on the transport of lithium batteries by air. Additional regulatory restrictions will have significant impacts on the ability of the medical device industry to provide their life-saving products to patients. Further bans on the transport of lithium ion and metal batteries will only serve to exacerbate the negative effect on public health by increasing the time necessary to ship products to a customer base that includes hospitals, schools, shopping centers, small businesses, residences, government buildings and public transportation facilities.

Why is Air Transport Vital?

The majority of lithium batteries used in medical devices are shipped by air. Due to new and pending transportation restrictions, the medical device supply chain is being disrupted, resulting in untimely shipping of life-sustaining and life-enhancing medical devices to patients. In many instances, critical shipments of life saving products must be transported for same day delivery. Additionally, air transport is the only option for many rural and remote locations around the globe. Sterile medical devices, for quality reasons, cannot be transported by ocean vessel due to heat, humidity, salt, and contaminants. Ocean shipping schedules are not reliable and are more often delayed as compared to air transport.

Hospitals and clinics, particularly those in remote areas only accessible by airplane, are already experiencing the impact of the recently adopted restrictions on lithium metal batteries. Hospitals and clinics are now required to establish safety stocks of expensive devices and backup batteries to serve their patients. Hospitals and clinics, already facing fiscal crisis, are absorbing the impacts from this inventory "safety stock" cost in order to respond to a slower and restricted supply chain process. The bottom-line is that the new restrictions are resulting in added hospitals costs without any offsetting benefit and are impeding time critical deliveries.

The MDBTC also requests that regulators consider the impacts additional restrictions will have on hospital and clinic returns of medical devices and their batteries. Upon notice of a suspected faulty

device, the FDA requires the manufacturer to complete a full diagnosis and report within 30 days. Hospitals and clinics – infrequent hazardous materials shippers – have difficulty navigating current transport requirements, leading to shipping delays and FDA scrutiny for medical device manufacturers. Additional restrictions will only serve to worsen this scenario.

Safety of Lithium Batteries Used in Medical Devices

Over the past decade, manufacturers of a wide variety of electrical devices have turned to lithium battery technology to enhance the power, battery life, and reliability of their products. While lithium cells and batteries are ubiquitous in our technology-forward culture, they are not without their risks. If subject to abnormal conditions, lithium batteries, both lithium metal and lithium ion, are capable of fire, and producing excessive heat and smoke. In response to these risks, regulators imposed requirements on the transport of lithium cells and batteries. These requirements have been modified throughout the years, often resulting in additional restrictions.

This tendency toward more stringent requirements is understandable when considering the regulator's base assumption: All lithium cells and batteries are created equal. From a regulatory perspective, it is convenient to group all lithium battery products together. However, there are variations in the safety of lithium cells and batteries based on design, manufacturing processes, tests, and oversight systems. For example, automated external defibrillators (AED) are portable medical devices that meet the highest standards and are required equipment aboard commercial passenger planes, per FAA mandate. With this document, it is our intent to educate regulators on the specifics of why the lithium cells and batteries used in medical devices are far safer when compared to standard consumer-type batteries.

Design

The lithium cells and batteries produced by member companies are manufactured for use in implantable and portable medical devices. The batteries are designed in accordance with an industry-wide philosophy of patient safety above all else. Lithium cells and batteries produced by member companies are designed to eliminate the potential for significant thermal events. Small and medium sized implantable cells are designed to have low intrinsic power and high internal resistance, meaning that in the unlikely event of internal or external short circuit the cell is incapable of producing enough energy to overheat.

For larger implantable batteries used in pacemakers, automated external defibrillators or neurological stimulators, the battery incorporates features to negate short circuits or overheating. Common design features in these batteries that are not typically found in consumer-type batteries include:

- Hermetic laser sealed can with glass to metal seals that are leak tested with helium gas to assure leak proof cells (consumer-type lithium primary cells are typically crimped sealed).
- Robust metallic case.
- Redundant separators and insulators to minimize internal shorts.
- Shutdown separators to maintain safety during an external short circuit.
- Design rules and equipment selection to mitigate foreign material contamination that extends from the materials supply chain to manufacturing.

The battery design is tested and revised multiple times during the development process. Tests include electrical, mechanical and environmental procedures. For instance, many batteries are designed in accordance with IEC standards 61960, 60601, 60086, and 62281. Additionally, manufacturers often meet UL standards for lithium cells or standards such as UL 2054 for lithium battery packs. At the battery pack level, UL 2054 includes safety concepts of:

- Single Component Fault on all electrical abuse tests;
- Temperature Test both for charge & discharge;
- Overvoltage Charge Test;
- Overcurrent Charge test;
- Pack-level cell imbalance Forced Discharge test;
- Cold Impact Test;
- High temperature Mold Stress test; and
- Limited Power Source test.

Material Supply Chain

The MDBTC believes that the safety of a lithium cell or battery is directly related to the quality of the materials used to construct the cell or battery. With this in mind, MDBTC member companies test all battery materials and components to ensure they are suitable for use. Additionally, these materials are only purchased from approved vendors. Vendors must be assessed and approved based on their ability to meet and maintain minimum requirements (e.g., FDA CFR 820/210/211, ISO 9001/13485/17025) and are audited by third-party organizations to verify these standards are being met. Typical sections that are covered in a supplier assessment include:

- Quality System & Management Responsibility
- Customer Orders & Agreements
- Supplier Control
- Quality Control
- Identification & Traceability
- Training
- Process Control
- Inspection & Testing
- Control of Measuring & Test Equipment
- Control of Nonconforming Material
- Corrective/Preventive Action & Complaint Handling
- Document Control
- Control of Records
- Outsourced Process

Assessments are carried out to initially approve the vendor and periodically thereafter, usually every 1-2 years, to ensure the continued suitability and performance of the supplier. Once approved, each new material or component that is sourced from that vendor must pass a rigorous qualification process. This process includes determination and verification of critical specifications for the material or component (including packaging and shipping requirements), evaluation of supplier's process capability and controls, development of incoming inspections and ongoing acceptance activities, and assurance of regulatory compliance for any restricted materials, if present.

Manufacturing

In keeping with their high safety standards, MDBTC members companies manufacture their batteries in environmentally controlled production rooms, free from the humidity and high levels of airborne particulate matter than can disrupt normal battery functions. Furthermore, engineers validate all equipment used during the manufacturing process in addition to validating that operational processes align with design requirements.

Quality Systems and Oversight

In order to ship lithium cells and batteries, each cell or battery must be of a type proven to meet the test requirements of the UN Manual of Tests and Criteria, Part III, Subsection 38.3. This requirement – common to all dangerous goods transportation standards – is the bare minimum of testing standards. Each MDBTC member company goes above and beyond these requirements when testing their cells and batteries.

Each MDBTC member company has a multifaceted quality management system in place to ensure their products meet the highest levels of performance and safety. Some quality management measures are undertaken due to governmental requirements, but member companies also voluntarily implement additional measures as a means to further enhance the safety and quality of their products.

There are various regulatory agencies that define requirements for the quality management systems of MDBTC member companies. The cells produced must be reviewed and approved by external medical device regulatory agencies before becoming a production product. Typical quality system processes include:

- Management Controls
- Production and Process Controls
- Corrective Action Preventive Action
- Document and Data Controls
- Material Controls
- Design Controls
- Product Approval
- Post Market Support

Process overviews, including high-level descriptions, inputs, outputs and process interactions are identified for each key quality system process. Primary activities supporting these key processes are identified as sub-processes and are documented in associated key Standard Operating Procedures (SOPs) and Working Instructions. Additionally, quality system processes are monitored, measured, and analyzed using various methodologies to ensure process effectiveness. Key process metrics are updated quarterly and reviewed against the established quality objectives. Metric management and other supporting actions that achieve planned results and ensure process effectiveness are required.

Government agencies like the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) strictly regulate medical devices. These devices undergo extensive testing, validation to

internationally recognized standards, and clinical studies that culminate in the review and clearance/approval by government agencies. In addition, medical devices comply with a range of international standards, guidelines and regulations. The FDA and other agencies have established systems requiring manufacturers to implement design controls that consider the safety of the device for its intended use, the assurance that devices withstand the rigors of shipping, and that each device reaches the user without being compromised.

The review processes for implantable and portable medical devices requires not only substantial clinical trials that may follow patients for years, but also painstaking review of how the devices and batteries used to power them are designed and manufactured. As part of the approval process, medical device lithium battery testing is performed under accelerated test conditions. These conditions exceed UN test requirements because they also account for patient safety. The testing qualification includes destructive examinations, thermal cycling, exposure to high pressure, mechanical shock, voltage/temperature, destructive analysis and solvent resistance. These batteries cannot be approved unless they pass these rigorous tests. Furthermore, proof of testing is required to be provided to regulators upon request.

Enhanced Enforcement

The majority of lithium cell or battery incidents involve products that are not in compliance with current regulations. Unfortunately, imposing further regulations will not improve compliance of those shippers who intentionally violate current requirements. Compliant shippers will be burdened by additional regulations while the non-compliant shippers will continue to ignore them. Improved enforcement of current regulations should be the first step in improving safety. Communication and coordination with industry groups and international government agencies would also aid compliance and enforcement. It has been shown that compliance with current regulations ensure safe transportation of lithium batteries by air.

After medical devices are approved, agencies such as the FDA regularly inspect the manufacturing sites to confirm that the products are manufactured according to what are known as "Good Manufacturing Practices" and/or "Quality System Regulations." These inspections are undertaken to ensure the uniform quality and safety of the devices. Moreover, the oversight agencies require medical device manufacturers to report any instance in which a device may have caused an adverse event in a patient. These agencies have authority to require the manufacturer to recall or repair devices that may pose safety issues if the manufacturer has not done so voluntarily.

The batteries and cells themselves are subject to rigorous internal testing procedures from MDBTC member companies. One hundred percent of batteries undergo inspections and electrical tests at numerous build processes along the operation. Also, visual inspections and electrical tests are conducted on one hundred percent of finished cells prior to offering them for transport. Finally, batteries and cells are sampled from manufacturing production according to a quality system on a continuous basis and placed on accelerated and real time life tests to ensure discharge performance criteria is met.

MDBTC members are aware of few, if any, instances in which a lithium battery in one of its products was associated with a fire or other hazard that has or could pose a risk in transport. Furthermore, one of our members verified they did not have a single lithium cell or battery event in their 45 years of operations.

Packaging

While there are variations in how each company ships lithium cells and batteries, all groups take extra care to ensure their shipments are securely packaged. Typically, cells are shipped in plastic trays with covers. Then, the assembled trays with covers are typically placed in appropriately sized fiberboard box with foam sheet separators. In some instances, the packaging includes temperature sensors on the inside to ensure that the batteries have not been exposed to extreme temperatures.

Next Steps

The ICAO DGP conducted technical meetings in April and July 2015 and will conclude its discussions at a DGP meeting in October 2015. During this meeting, regulatory requirements and potential additional restrictions will be incorporated in the 2017-2018 edition of the ICAO TI, effective from January 1, 2017.

The MDBTC members are interested in working with regulators and ICAO to develop risk-mitigating strategies that can be implemented without unnecessary impacts on health care systems and patients. While the MDBTC promotes safety, it is imperative to ensure that regulators understand the supply chain logistics associated with the transport of medical devices and seek reasonable alternatives to avoid unnecessary and overly burdensome regulatory requirements.

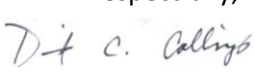
Best Practices

The MDBTC wishes to work with regulators to develop practical regulations governing the transport of lithium cells and batteries used in medical devices. This council acknowledges that there are different paths to reaching this goal. A few of the options the MDBTC would consider are:

- Enhanced packaging standards.
- Incentivizing additional quality controls for battery manufacturers.
- Adding specific UN numbers and corresponding Packing Instructions to accommodate cells and batteries used in medical devices.
- Requirements incentivizing battery manufacturers to increase oversight.
- Modification of transport requirements for companies that show completion of tests beyond the minimum UN Manual of Tests and Criteria, Part III, Subsection 38.3 standard.
- Modifying requirements based on energy density or differing chemistries of the cells or batteries.
- Consideration of an independent safety oversight process that accounts for those already in place.

The council appreciates your time and consideration of these issues. We look forward to working together in the future to find practical solutions that enhance transportation safety without overly burdening manufacturers of medical devices and the lithium cells and batteries that power them.

Respectfully,





David Collings	**Steven LaPierre**	**Bill Withrow**	**Kathleen O'Shei**	**Aaron Jorgensen**
Philips Healthcare	*Boston Scientific*	*Baxter Healthcare*	*Greatbatch*	*Medtronic*

BYLAWS
OF THE
MEDICAL DEVICE BATTERY TRANSPORT COUNCIL, INC.

Article I. Name, Purpose and Offices

Section 1. Name. The name of the corporation is the Medical Device Battery Transport Council, Inc., or MDBTC.

Section 2. Definition. A medical device is any instrument, apparatus, implement, machine, appliance, implant, material or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- orthopedic appliances; artificial parts of the body; hearing aids and other appliances which are worn or carried, or implanted in the body, to compensate for a defect or disability;
- aids for disabled/handicapped people;
- accessories for medical devices (accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose).

Section 3. Purpose. MDBTC represents the lithium battery-powered medical device industry sector comprised of manufacturers of batteries used to power medical devices and the battery-powered medical devices. MDBTC's mission is to work collectively to educate government regulators and other people involved with the development, implementation and enforcement of lithium battery transport regulations, to ensure that such regulations do not unnecessarily restrain or delay medical device supply chains, adversely impact public health or compromise transport safety.

Section 4. Principal Office. The Principal Office of the corporation in the Commonwealth of Virginia (hereinafter, "the Commonwealth") shall be located in the City of Manassas. The corporation may have such other business offices, either within or without the Commonwealth, as the Board of Directors (hereinafter, "the Board") may determine or as the affairs of the corporation may require.

Section 5. Registered Office. The corporation shall maintain in the Commonwealth a Registered Office and a Registered Agent whose office is identical with the Registered Office as required by the laws of the Commonwealth. The Registered Office of the corporation may be, but need not be, identical with the Principal Office in the Commonwealth, and the address of the registered office may by resolution be changed from time to time by the Board.

Article II. Board of Directors

Section 1. General Powers. The business, property and affairs of the corporation shall be managed by its Board of Directors. Directors need not be residents of the Commonwealth.

Section 2. Number, Tenure and Qualifications. The number of directors of the corporation shall be no fewer than three and no more than nine. The term of each director shall be two years, commencing April 1 of the year of election and ending March 31 of the second following year, or until his or her successor shall have been elected and qualified. Each director shall hold office until his or her successor shall have been elected and qualified.

Section 3. Leadership. The directors shall as necessary at a regular annual meeting or at a special meeting elect one of their number to serve as Executive Director and another to serve as Chair of the Board during his or her respective term. The Chair or, in his or her absence, the Executive Director, shall preside at meetings of the Board and appoint such committees and committee chairs as necessary.

Section 4. Regular Meetings. A regular annual meeting of the Board shall be held on the 1st day in the month of April in each year, beginning with the year 2016, at the hour of l:00 p.m. Eastern Time without other notice than required by this bylaw. If the day fixed for the annual meeting shall be a legal holiday in the Commonwealth, the meeting shall be held on the next succeeding business day. The Board may provide by resolution the time and place, either within or without the Commonwealth, for the holding of additional regular meetings of the Board without other notice than such resolution.

Section 5. Special Meetings. Special meetings of the Board may be called by or at the request of any two directors. Those directors may fix any place, either within or without the Commonwealth, as the place for holding any special meeting of the Board called by them.

Section 6. Notice. Notice of any special meeting of the Board shall be given at least two days previously thereto by written notice delivered personally or sent by postal or electronic mail. Any director may waive notice of any meeting. The attendance of a director at a meeting shall constitute a waiver of notice of such meeting except where a director attends a meeting for the express purpose of objecting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the Board need be specified in the notice or waiver of notice of such meeting.

Section 7. Quorum. A majority of the number of directors fixed and serving in accordance with section 2 of this Article II shall constitute a quorum for the transaction of business at any meeting of the Board, but if less than such majority is present at a meeting, a majority of the directors present may adjourn the meeting from time to time without further notice.

Section 8. Manner of Acting. The act of the majority of the directors present at a meeting at which a quorum is present shall be the act of the Board, unless the act of a greater number is required by law or by these Bylaws.

Section 9. Removal. Any director may be removed by the Board whenever in its judgment the best interests of the corporation will be served thereby.

Section 10. Vacancies. Any vacancy occurring in the Board and any directorship to be filled by reason of an increase in the number of directors, shall be filled by the affirmative vote of a majority of the remaining directors though less than a quorum of the Board. A director elected to fill a vacancy shall be elected for the unexpired term of his or her predecessor in office.

Section 11. Compensation. Directors as such shall not receive any stated salaries for their services but, by resolution of the Board, a fixed sum and expenses of attendance, if any, may be allowed for attendance at each regular or special meeting of the Board. No such payment shall preclude any director from serving the corporation as Executive Director, as an officer, or in any other capacity and receiving compensation therefor.

Section 12. Informal Action. Any action required by law to be taken at a meeting of directors, or any action which may be taken at a meeting of the Board, may be taken without a meeting if a consent in writing, setting forth the action so taken, shall be signed by all of the directors.

Article III. Officers

Section 1. Number. The officers of the corporation shall include a Secretary, a Treasurer and such other officers as may be elected by the Board in accordance with the provisions of this article. The Board may elect or appoint such other officers as it shall deem desirable, to have the authority and perform duties prescribed by the Board. Any two or more offices may be held by the same person.

Section 2. Election and Term of Office. The officers of the corporation shall be elected annually by the Board at its regular annual meeting. If the election of officers shall not be held at such meeting, it shall be held as soon thereafter as is convenient. Each officer shall hold office until his successor shall have been duly elected and shall have qualified or until his death or until he shall resign or shall have been removed in the manner hereinafter provided.

Section 3. Removal. Any officer or agent may be removed by the Board whenever in its judgment the best interests of the corporation will be served thereby, but such removal shall be without prejudice to the contract rights, if any, of the person so removed. Election or appointment of an officer or agent shall not of itself create contract rights.

Section 4. Vacancies. A vacancy in any office because of death, resignation, removal, disqualification or otherwise, may be filled by the Board for the unexpired portion of the term.

Section 5. The Treasurer. If required by the Board, the treasurer shall give a bond for the faithful discharge of his or her duties in such sum and with such surety or sureties as the board of directors shall determine. The treasurer shall: (a) have charge and custody of and be responsible for all funds and securities of the corporation; (b) receive and give receipts for moneys due and payable to the corporation from any source, and deposit all such moneys in the name of the corporation in such banks, trust companies or other depositaries as shall be selected in accordance with the provisions of Article IV of these bylaws; and (c) in general perform all of the duties incident to the office of treasurer and such other duties as from time to time may be assigned by the Board.

Section 6. The Secretary. The secretary shall: (a) keep the minutes of the proceedings of the Board in one or more books provided for that purpose; (b) see that all notices are duly given in accordance with the provisions of these bylaws or as required by law; (c) be custodian of the corporate records and of the seal of the corporation and see that the seal of the corporation is affixed to all documents the execution of which on behalf of the corporation under its seal is authorized in accordance with the provisions of these bylaws; and (d) in general perform all duties incident to the office of secretary and such other duties as may be assigned by the president or by the Board.

Article IV. Contracts, Checks and Deposits

Section 1. Contracts. The Executive Director may authorize any officer or officers, agent or agents of the corporation, in addition to the officers so authorized by these bylaws, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the corporation, and such authority may be general or confined to specific instances.

Section 2. Checks, Drafts, Etc. All checks, drafts or other orders for the payment of money, notes or other evidences of indebtedness issued in the name of the corporation shall be signed by the officers or agents of the corporation and in such manner as shall be determined by resolution of the Board.

Section 3. Deposits. All funds of the corporation shall be deposited to the credit of the corporation in such banks, trust companies or other depositaries as the Treasurer may select.

Section 4. Gifts. The Treasurer may accept on behalf of the corporation any contribution, gift, bequest or devise for the general purpose or for any special purpose of the corporation.

Article V. Books and Records

The corporation shall keep correct and complete books and records of account and shall also keep minutes of the proceedings of its Board and committees having any of the authority of the

Board. All books and records of the corporation may be inspected by any member of the Board, or their agents or attorneys for any proper purpose at any reasonable time.

Article VI. Fiscal Year

The fiscal year of the corporation shall begin on the 1st day of January and end on the 31st day of December in each year.

Article VII. Seal

The Board shall provide a corporate seal which shall be circular in form and shall have inscribed thereon the name of the corporation and the Commonwealth of Virginia and the words "Corporate Seal."

Article VIII. Waiver of Notice

Whenever any notice is required to be given under the provisions of these Bylaws or under the provisions of the Articles of Incorporation or under the laws of the Commonwealth, a waiver in writing signed by the person or persons entitled to such notice, whether before or after the time stated therein, shall be deemed equivalent to the giving of such notice.

Article IX. Amendments to Bylaws

These Bylaws may be altered, amended or repealed and new bylaws may be adopted upon the two-thirds vote of the Board at any regular or special meeting, if at least thirty days written notice is given of intention to alter, amend or repeal or adopt new Bylaws at the meeting.

Article X. Antitrust Policy

The board shall, with advice of counsel, adopt a written policy for strict compliance with the antitrust laws of the United States and the business competition laws of other nations. Each meeting of the Board shall begin with a reminder of the need for strict compliance with such laws.

Article XI. Conflict-of-Interest Policy

The Board shall, with advice of counsel, adopt a written conflict-of-interest policy and shall require each member of the Board, upon election and at least annually thereafter, to certify in writing their compliance with such policy.

Adopted by the Board of Directors of the Medical Device Battery Transport Council, Inc., April 4, 2016.

Commonwealth of Virginia

STATE CORPORATION COMMISSION

Richmond, April 12, 2016

This is to certify that the certificate of incorporation of

Medical Device Battery Transport Council, Inc.

was this day issued and admitted to record in this office and that the said corporation is authorized to transact its business subject to all Virginia laws applicable to the corporation and its business. Effective date: April 12, 2016

State Corporation Commission
Attest:

Joel H. Peck
Clerk of the Commission

CISCCJ

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 04-04-2016

Employer Identification Number:
81-2076880

Form: SS-4

Number of this notice: CP 575 E

MEDICAL DEVICE BATTERY TRANSPORT
COUNCIL INC
10036 LAKE OCCOQUAN DR
MANASSAS, VA 20111

For assistance you may call us at:
1-800-829-4933

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 81-2076880. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

When filing tax documents, payments, and related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear-off stub and return it to us.

When you submitted your application for an EIN, you checked the box indicating you are a non-profit organization. Assigning an EIN does not grant tax-exempt status to non-profit organizations. Publication 557, Tax-Exempt Status for Your Organization, has details on the application process, as well as information on returns you may need to file. To apply for recognition of tax-exempt status under Internal Revenue Code Section 501(c)(3), organizations must complete a Form 1023-series application for recognition. All other entities should file Form 1024 if they want to request recognition under Section 501(a).

Nearly all organizations claiming tax-exempt status must file a Form 990-series annual information return (Form 990, 990-EZ, or 990-PF) or notice (Form 990-N) beginning with the year they legally form, even if they have not yet applied for or received recognition of tax-exempt status.

Unless a filing exception applies to you (search www.irs.gov for Annual Exempt Organization Return: Who Must File), you will lose your tax-exempt status if you fail to file a required return or notice for three consecutive years. We start calculating this three-year period from the tax year we assigned the EIN to you. If that first tax year isn't a full twelve months, you're still responsible for submitting a return for that year. If you didn't legally form in the same tax year in which you obtained your EIN, contact us at the phone number or address listed at the top of this letter.

For the most current information on your filing requirements and other important information, visit www.irs.gov/charities.

(IRS USE ONLY) 575E 04-04-2016 MEDI O 9999999999 SS-4

IMPORTANT REMINDERS:

* Keep a copy of this notice in your permanent records. **This notice is issued only one time and the IRS will not be able to generate a duplicate copy for you.** You may give a copy of this document to anyone asking for proof of your EIN.

* Use this EIN and your name exactly as they appear at the top of this notice on all your federal tax forms.

* Refer to this EIN on your tax-related correspondence and documents.

* Provide future officers of your organization with a copy of this notice.

Your name control associated with this EIN is MEDI. You will need to provide this information, along with your EIN, if you file your returns electronically.

If you have questions about your EIN, you can contact us at the phone number or address listed at the top of this notice. If you write, please tear off the stub at the bottom of this notice and include it with your letter. Thank you for your cooperation.

Keep this part for your records. CP 575 E (Rev. 7-2007)

Return this part with any correspondence so we may identify your account. Please correct any errors in your name or address.

CP 575 E

9999999999

Your Telephone Number
( ) -
_____

Best Time to Call
_____

DATE OF THIS NOTICE: 04-04-2016
EMPLOYER IDENTIFICATION NUMBER: 81-2076880
FORM: SS-4 NOBOD

INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

MEDICAL DEVICE BATTERY TRANSPORT
COUNCIL INC
10036 LAKE OCCOQUAN DR
MANASSAS, VA 20111