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WORKING PAPER

DANGEROUS GOODS PANEL (DGP)
MEETING OF THE WORKING GROUP OF THE WHOLE

Rio de Janeiro, Brazil, 20 to 24 October 2014

Agenda Item 5: Review of provisions for the safe transport of lithium batteries
5.6: Miscellaneous lithium battery issues

FURTHER RESTRICTIONS ON THE TRANSPORT OF MEDICAL DEVICES ABOARD AIRCRAFT

(Presented by the Dangerous Goods Advisory Council (DGAC))

SUMMARY

The DGP is requested to consider the implications of further restrictions on the transport of medical devices aboard aircraft to patient health and the development of new devices that enhance public health.

Action by the DGP-WG is in paragraph 2.

1. INTRODUCTION

1.1 DGAC members include some of the largest medical device manufacturers that are global leaders in medical device technology. These companies develop and manufacture a wide range of life-extending, life-sustaining and life-enhancing products and therapies with emphasis on providing a complete continuum of care to diagnose, prevent and monitor chronic conditions such as debilitating cardiac rhythm disorders, spinal, diabetes, cardiovascular and neurological chronic disease states. These devices include implantable pacemakers, defibrillators, and neurostimulators many of which are powered by lithium ion and lithium metal batteries. The devices are also used for relieving pain through spinal stimulation, administering cancer treating and pain relieving drugs through implantable drug pumps, providing insulin through diabetic pumps and providing deep brain stimulation for chronic movement disorders. Medical devices containing lithium batteries are required to meet high standards of quality and performance due to the fact that failure of a device generally will have life threatening implications. These devices are only offered to the public after years of research and development and being subject to clinical trials, regulatory oversight, compliance with rigorous standards and testing.

1.2 DGAC members recognize ICAO's role in addressing the risk associated with dangerous goods aboard aircraft. DGAC also shares concerns related to incidents that have occurred in

transportation and supports ICAO's efforts to develop mitigation strategies to ensure that the ICAO Technical Instructions provides an acceptable risk for lithium battery shipments. Nevertheless DGAC suggests that additional consultation and participation by representatives of segments of the population that are impacted by the decisions taken is necessary to ensure clear, effective and appropriate regulations are developed. It is critical that the regulations are developed through a process that allows input from all industry sectors so that appropriate alternatives can be implemented by states, enforced and understood by shippers and carriers alike. DGAC believes that these decisions should take into account the implications to supply chains and on other segments of society including issues related to the preservation of human life and preventing injuries and fatalities outside of the aviation community. Restrictions that are implemented without appropriate consideration of the implications outside of aviation safety could have serious and adverse impacts to public safety and health. For instance, lithium batteries are used in medical devices, weather monitoring and warning systems, surveillance, disaster relief, emergency response and security equipment among other applications. A regulation reducing a target risk for one area of focus may increase other risks ultimately resulting in greater loss of life, harm to the environment and to economies. Safety agencies must be careful to avoid overlooking countervailing risks and examine potential risk trade-offs.

1.3 DGAC recognizes that 14 recommendations were developed based on the Second Multi-Disciplinary Meeting on Lithium Battery Transport that was held on September 9 – 11 in Cologne, Germany. DGAC applauds ICAO involving disciplines other than dangerous goods in the discussions but would respectively suggest that there are other disciplines that may be impacted by decisions taken by the Dangerous Goods Panel (DGP), (e.g. health care and medical device manufacturers) which should be involved in the future. DGAC is also concerned that significant decisions have been taken by the DGP at specially scheduled meetings at the end of the biennium and, unavoidably, public consultation is limited and there is little opportunity for industry to assess unforeseen implications since many decisions are based on discussions during the meetings based on the production of numerous flimsies in efforts to achieve consensus. It is important that parties that may be significantly affected are able to at least convey to the Panel the implications of any decisions and offer alternative solutions, which may not be immediately apparent. DGAC believes that appropriate consultation results in the development of more effective regulations that address the root causes of incidents with minimal unnecessary burden on vital supply chains that also impact human life and well-being. Regulations that are developed without appropriate consideration and consultation tend to be overly complex resulting in less compliance, reduction in risk, enhanced safety and may result in unforeseen social impacts that have negative consequences to human populations. Overly complicated regulations lead to non-compliance and increase the likelihood that unscrupulous shippers will offer undeclared and non-compliant cargo. On this basis, DGAC encourages the DGP to be deliberate and allow sufficient time prior to adopting amendments for consultation and appropriate feedback.

1.4 DGAC also applauds ICAO's recognition that outreach and enforcement of existing regulations are key elements to reducing risk and the likelihood of incidents. We share the concerns about the apparent lack of enforcement by some States of the lithium battery provisions in the ICAO Technical Instructions and fully support Recommendation 5/3 that was drafted in April 2014 by the DGP Working Group on Lithium Batteries and addresses the issues associated with non-compliant lithium battery shipments. DGAC suggests that ICAO consider conducting an evaluation of the effectiveness of the regulations that have been promulgated in the Technical Instructions over the past 4-6 years and to consider their effectiveness to reducing incidents. As several Panel members have indicated, imposing more regulation may not improve compliance of those shippers who intentionally violate current regulations. Compliant shippers are burdened with new regulations resulting in the expenditure of significant resources while non-compliant shippers continue to ignore the law. Shippers that continue to offer non-compliant shipments to air carriers need to be held accountable for their actions and penalized as appropriate as a means of changing behaviors that result in placing the public at risk. It would be useful

to better understand the quantities of undeclared and non-compliant lithium battery shipments that are offered by shippers to airlines today and the impact that increased restriction may have on the behaviour of these shippers. Understanding that even with the best safety oversight efforts aircraft may have undeclared shipments of lithium batteries is reason to ramp up the efforts to implement mitigation strategies that focus on enhancing fire suppression and detection systems. DGAC encourages ICAO to carefully consider any further restrictions on the transport of lithium batteries and their overall implications beyond aviation safety and to enhance public consultation.

1.5 External defibrillators (AEDs) present an excellent example of the necessity to ship replacement batteries in a timely manner. In a future paper DGAC will provide additional examples of both implantable and non-implantable devices and how restrictions on transport aboard aircraft will impact supply chains and the ability to get products to patients. Bans on the transport of lithium ion or metal batteries would have a significant negative effect on public health, by increasing the time necessary to ship replacement batteries to customers including hospitals, schools, shopping centers, places of business, residences, government buildings and public transportation facilities. To date, this year one AED manufacturer has already safely shipped more than 100,000 lithium metal AED batteries to customers by air. These air shipments have enabled customers to quickly put an AED back into service, or prevent an AED with a low battery from being taken out of service. This has potentially enabled lives to be saved. Drastically increasing the transit time for these batteries could leave AEDs needing replacement batteries in a non-functional state and therefore not available for use in an emergency. Surviving sudden cardiac arrest is dependent on how quickly a victim is defibrillated. For each minute that defibrillation is delayed, the victim's chance of survival decreases by 7 – 10%. For victims of sudden cardiac arrest, a shock from a defibrillator is the most effective way to restore the heart's normal pumping rhythm. The end result could be increased deaths because the AED could not be deployed.

2. ACTION BY THE DGP-WG

2.1 The DGP-WG is invited to carefully consider alternatives to unnecessary restrictions on lithium battery powered equipment including medical devices. Major medical device manufactures ship both lithium metal and lithium ion batteries and batteries contained in equipment. These devices are manufactured to standards and performance criteria and packaged using methods that exceed those currently required by the ICAO Technical Instructions and UN Model Regulations. Additionally, these devices are manufactured under strict quality assurance programs. Failure of a medical device has life threatening consequences and companies that manufacture them go to great lengths to prevent defects and to ensure that they are not damaged during transport. Manufacturers of devices subject their batteries and devices to tests and rigorous quality checks prior to shipping to ensure that the devices are of high integrity and have been manufactured to the strict standards that prevent the likelihood of internal short circuit that could result in thermal runaway. DGAC favors enhancing packaging requirements over imposing restrictions on transport aboard aircraft and encourages the ICAO to consider the robust packaging used by the medical device community. One of our members has shipped over eight million medical device lithium cells over the last 10 years and has not experienced even one incident.

2.2 DGAC intends to submit a paper for the 2015 DGP Working Group to provide information related to the design, manufacture and testing of medical devices as well as information related to potential impacts to supply chains and public health on behalf of members that manufacture and distribute medical devices. The paper will provide information related to the range of international standards, competent authority requirements and regulations that apply. International electrical medical device standards establish safety, design, and performance requirements as well as requirements for risk analysis and mitigation. Competent authorities have established guidance for various medical devices

outlining specific performance testing. For instance, the U.S. Federal Drug Administration (FDA) Quality System Regulation (QSR) requires manufacturers to implement design controls that mandate the consideration of issues that include the safety of the device for its intended use, the assurance that devices withstand the rigors of shipping and reach the user without compromise. The QSR also establishes regulations for manufacturing medical devices, including requirements for documented specifications, productions records, failure investigation, complaint investigation, and operator training. These requirements need to be considered when establishing requirements for medical devices. DGAC appreciates the opportunity to participate in the DGP's deliberations on this critical safety issue.

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