International Civil Aviation Organization

DGP-WG/15-WP/21
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WORKING PAPER

DANGEROUS GOODS PANEL (DGP) WORKING GROUP MEETING (DGP-WG/15)

Montreal, 27 April to 1 May 2015

Agenda Item 2: Development of recommendations for amendments to the *Technical Instructions for the Safe Transport of Dangerous Goods by Air* (Doc 9284) for incorporation in the 2017-2018 Edition

2.3: Part 3 — Dangerous Goods List, Special Provisions and Limited and Excepted Quantities

REQUIREMENTS FOR STERILIZATION DEVICES CONTAINING NITROGEN DIOXIDE, NITRIC OXIDE OR NITRIC ACID

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

SUMMARY

The DGP is requested to consider adopting special provisions similar to Special Provision A131 for the transport sterilization devices containing nitrogen dioxide, nitric oxide or nitric acid. In order to be responsive to incidents involving the need for non-electrical reliant sterilization devices, the devices must be able to be transported by both passenger and cargo aircraft.

Action by the DGP-WG: The DGP-WG is invited to consider incorporating a new special provision assigned to UN 2037 — **Receptacles, small, containing gas** (toxic, oxidizing & corrosive) without a release device, non-refillable and UN 2031 — **Nitric acid**, other than red fuming, with at least 65% but not more than 70% nitric acid, to authorize the transport of sterilization devices containing these gases aboard passenger and cargo aircraft.

1. INTRODUCTION

1.1 The Dangerous Goods Advisory Council (DGAC) submitted a working paper to the previous working group meeting that was held in Rio de Janiero (DGP-WG/14, 20 October to 24 October 2014) to address sterilization devices (see paragraph 3.2.3.3 of the DGP-WG/14 report). DGAC is submitting the proposals in this paper on the basis of comments received at DGP-WG/14. This proposal addresses the transport of sterilization devices required for medical response in disaster relief that contain:

a) **Nitrogen dioxide** — UN 1067;

b) **Nitric oxide, compressed** — UN 1660: and

c) **Nitric acid,** other than red fuming, with more than 20% but less than 65% nitric acid, UN 2031, PG II

1.2 Sterilization with the gases or liquids referred to in this paper does not require electricity and offers improved compatibility and safety over other materials used for sterilization of medical equipment and devices. The gases are common, well-studied gases that while toxic at high concentrations present a lower risk than other sterilant gases such as ethylene oxide or chlorine dioxide. The gases are compatible with most reusable medical equipment as well as many drug-device combination products and are extremely effective against bacteria, viruses, and spores. Their relatively low saturated vapour pressures and boiling points coupled with the low concentrations employed during sterilization translate into improved safety. Although toxic in high concentrations, there is little risk in transport or to personnel using the equipment because the quantity of material is minimal and the intended packaging is robust including metal pressure receptacles placed in intermediate and outer packaging tested to the Packing Group I performance level. Additionally an absorbent material is placed in the intermediate packaging that is capable of absorbing and neutralizing any risk of its release from the outer packaging. The nitric acid is authorized on cargo aircraft but is not authorized for passenger aircraft.

1.3 As indicated in our previous paper, DGAC is interested in including provisions in the Technical Instructions for the transport of sterilization devices using the dangerous goods described herein. The provisions proposed are based on comments received from DGP members and are patterned after the provisions currently in Special Provision A131 except that the gases will be contained in metal receptacles with a burst pressure of at least 7000 psi. Each hermetically sealed inner metal gas cartridge will be designed with a safety factor (burst pressure/working pressure) of at least 4 times the working pressure of the receptacle. Each gas cartridge will be individually inspected for leakage after filling. The maximum mass of contents per litre of water capacity (filling factor) will be equal to 0.95 times the density of the liquid phase at 50°C and the liquid phase will not fill the gas cartridge at any temperature up to 60°C. The test pressure of the gas cartridge will be at least equal to the vapour pressure (absolute) of the liquid at 65°C, minus 100 kPa (1 bar). Gas cartridges will be packaged in a sealed compatible intermediate packaging with an absorbent material capable of absorbing any leaked material. Inner and intermediate packagings will be placed in a rigid outer packaging that meets the Packing Group I performance standard. The gas cartridges will not contain more than 50 mL per hermetically sealed inner gas cartridge with not more than 1 litre per outer packaging. The nitric acid, UN 2031 would similarly be transported in inner and intermediate packagings placed in a rigid outer packaging that meets the Packing Group I performance level.

2. BACKGROUND

2.1 The number of people affected by natural disasters has grown as the world population has increased. Growing urbanization combined with poor infrastructure in developing countries has often translated into tragedy. Developed countries are not exempt from severe social and health disruptions following natural disasters. The United States, Philippines, Pakistan, China, Haiti, and Japan, to name only a few cases, have all recently faced large-scale disasters that wreaked havoc on the lives of millions. Relief organizations and governments struggle to provide medical care for those affected by disasters. Resources are inherently limited and conditions are challenging. As World Health Organization (WHO) guidelines emphasize, sterilization and re-use of instruments is essential in emergency medical care in disaster scenarios, but medical teams operating in these environments are often forced to improvise resulting in cross-contamination of instruments and high rates of disease transmission to patients and healthcare workers.

2.2 Existing healthcare facilities in Liberia, Guinea and Sierra Leone are resource challenged and have therefore failed to contain the Ebola outbreak. MSF (Doctors without Borders) has developed an extensive infection protection protocol for Ebola Virus Disease (EVD) outbreaks. They recommend the use of dedicated equipment exclusively assigned to EVD patient care areas, with equipment, such as stethoscopes, used on a single patient exclusively. The portable nature of the EPS allows for immediate point-of-care sterilization of items at the bedside, supporting MSF's recommended single patient use practice for medical instruments. This would help reduce risk of surface transmission. EPS sterilization of dedicated medical equipment would also help prevent cross-infection of patients with different Ebola strains, reducing opportunities for viral mutation. Healthcare workers have been disproportionately adversely impacted by Ebola outbreaks. EPS sterilization would help prevent healthcare-associated infection of health workers.

2.3 The provision of safe surgical care has a few basic requirements that present problems in low-resource settings. Surgery cannot be performed safely and effectively without sterile instruments, anesthesia delivery, and trained personnel. Traditional methods of instrument sterilization and anesthesia delivery require a large input of electricity (which is commonly inaccessible or unreliable), and many African countries face severe shortages of surgeons. These issues are being addressed through innovations that make surgery possible without electricity or the presence of a certified surgeon. Non-physician clinicians with high-levels of training can now perform simple procedures in some countries, and anesthesia machines that can operate independent of electricity have been developed and introduced to low-resource healthcare settings.

2.4 Unfortunately, an alternative to the autoclave for sterilization, which requires large amounts of electricity, still is not widely available. As a result, many healthcare facilities cannot sterilize their instruments, and must resort to disinfection with boiling water or other disinfectants, an inadequate approach for safe surgical procedures and the containment of infectious diseases.

2.5 The lack of proper sterilization for surgical procedures often leads to the development of a life-threatening or debilitating infection. Healthcare-associated infection is a major problem for hospitals all over the world, affecting hundreds of millions of people every year, and costing healthcare systems billions of dollars. Although no data exist on the rates of these infections in the developing world, it is estimated that they occur much more frequently in low- and middle- income countries than in the developed world. The ability to properly sterilize medical and surgical tools without electricity will lower the incidence of these infections, and expand access to essential surgical procedures.

2.6 In order to be responsive to incidents involving the need for non-electrical reliant sterilization devices, the devices must be able to be transported by both passenger and cargo aircraft.

3. ACTION BY THE DGP-WG

3.1 The DGP-WG is invited to:

a) consider incorporating a new Special Provision assigned to UN 2037 — **Receptacles, small, containing gas** (toxic, oxidizing & corrosive) without a release device, non-refillable, to authorize the transport of sterilization devices containing these gases aboard passenger and cargo aircraft.

b) consider incorporating a new Special Provision to UN 2031, **Nitric acid**, other than red fuming, with at least 65% but not more than 70% nitric acid, PG II to authorize

the transport of sterilization devices containing these gases aboard passenger and cargo aircraft.

The new special provisions would read as shown in the appendix to this working paper.

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APPENDIX

PROPOSED AMENDMENT TO PART 3 OF THE TECHNICAL INSTRUCTIONS

Part 3

DANGEROUS GOODS LIST, SPECIAL PROVISIONS AND LIMITED AND EXCEPTED QUANTITIES

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Chapter 3

SPECIAL PROVISIONS

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Table 3-2. Special provisions

TIs	*UN*	
AXXX		Sterilization devices when containing less than 50 mL per inner gas cartridge and not more than 1 L per outer packaging of UN 1067 — **Nitrogen dioxide** or UN 1660 — **Nitric oxide, compressed** may be transported on passenger and cargo aircraft provided that the following conditions are met: a) each inner metal gas cartridge must be designed with a safety factor of at least four times the working pressure of the receptacle; b) each gas cartridge must be packaged with an absorbent material capable of absorbing any leaked material in a sealed compatible intermediate packaging capable of containing any released gas; c) inner packagings must be placed in a rigid outer packaging that meets the Packing Group I performance level; and d) transport on passenger aircraft is only permitted for disaster response operations in limited circumstances when cargo aircraft flights are not available. The statement “Sterilization devices for medical response in accordance with Special Provision AXXX” must be: a) included on the dangerous goods transport document;and b) marked on the package.

TIs	*UN*	
AYYY		Sterilization devices when containing less than 50 mL in glass or metal inner packagings with not more than 1 L per outer packaging of UN 2031 — **Nitric acid**, other than red fuming, with more than 20% and less than 65% nitric acid, Packing Group II may be transported on passenger and cargo aircraft provided the following conditions are met: a) each inner packaging must be packaged with an absorbent material capable of absorbing any leaked material in a sealed compatible intermediate packaging capable of containing any released liquid; and b) inner packagings must be placed in a rigid outer packaging that meets the Packing Group I performance level. The statement “Sterilization devices for medical response in accordance with Special Provision AYYY” must be: a) included on the dangerous goods transport document; and b) marked on the package.

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