International Civil Aviation Organization

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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 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 OR NITRIC OXIDE

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

SUMMARY

The DGP is requested to consider adopting a special provision similar to A131 for the transport sterilization devices containing Nitrogen Dioxide or Nitric Oxide.

Action by the DGP-WG: The DGP-WG is invited to consider incorporating a new special provision assigned to UN 1067 **Nitrogen dioxide** and UN 1660 **Nitric oxide, compressed** to authorize the transport of sterilization devices containing these gases aboard passenger and cargo aircraft. DGAC is requesting comments to facilitate the development of a formal paper for the 2015 meeting of the Working Group of the Whole.

1. INTRODUCTION

1.1 Special Provision A131 is assigned to "UN 1040 **Ethylene Oxide**" in the Table 3-1, Dangerous Goods List. A131 provides for the transportation of sterilization devices that contain small quantities of ethylene oxide in glass ampoules or capsules as excepted quantities. Ethylene oxide is a toxic and flammable gas that has also been reported to have carcinogen characteristics. Recently sterilization devices that contain other materials have been developed. A DGAC member is developing a power independent sterilization device using the following dangerous goods to be used in emergency and disaster response scenarios including low resource environments where electric power may not be readily available:

a) UN 1067 **Nitrogen dioxide** (NO2); and

b) UN 1660 **Nitric oxide, compressed**;

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

1.2 Sterilization with these gases or liquids 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 hydrogen peroxide, 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 outer packaging tested to the Packing Group I performance level. These gases are effective sterilants at low concentrations, often between 8 and 10 mg/L and typically less than 21mg/L, depending on the application. They are non-explosive and non-flammable. The liquid sterilant is authorized on cargo aircraft and can be transported in accordance with Packing Instruction 855.

1.3 For decades hospitals and medical device manufacturers have sterilized their products using ethylene oxide, radiation (gamma or e-beam), or heat (steam or dry) processes. In resource-limited settings ranging from the developing world, to the battlefield, to the aftermath of a major natural disaster, the limitations of these sterilization technologies has been observed and documented. Despite improvements and refinements, inherent limitations persist: the need for electricity and water, material compatibility, high costs, long sterilization cycles, sterilant residues, high temperatures, and operator risk. Sterilization devices that utilize **Nitrogen dioxide**, UN1067, **Nitric oxide compressed**, UN 1660 or **Nitric acid**, UN 2031, Packing Group II provide alternatives to the current systems without the many limitations. These systems will provide a vital life line for performing medical procedures in low resource environments and will save lives.

1.4 DGAC is interested in including provisions in the Technical Instructions for the transport of these sterilization devices. The provisions will be patterned after the provisions currently in A131 except that the gases will be contained in metal receptacles that will be designed with a 4:1 safety factor in quantities not exceeding 30 ml per inner metal receptacle and 500 ml per outer package that are placed in rigid outer packagings meeting the Packing Group I performance level. The **nitric acid**, UN 2031 would be transported in inner packagings consistent with the requirements in Part 3;5.1 placed in a rigid outer packaging that meets the Packing Group I performance level.

2. ACTION BY THE DGP-WG

2.1 The DGP-WG is invited to consider incorporating a new special provision assigned to UN 1067 and UN 1660 to authorize the transport of sterilization devices containing these gases aboard passenger and cargo aircraft. DGAC is requesting comments to facilitate the development of a formal paper for the 2015 meeting of the Working Group of the Whole.

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APPENDIX A

PROPOSED AMENDMENT TO PART 3 OF THE TECHNICAL INSTRUCTIONS

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Part 3

DANGEROUS GOODS LIST, SPECIAL PROVISIONS AND LIMITED AND EXCEPTED QUANTITIES

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Chapter 3

SPECIAL PROVISIONS

Parts of this Chapter are affected by State Variations AE 3, AU 1, AU 2, CA 7, HR 3, IR 3, JM 1, KP 2, MO 2, NL 1, US 11, ZA 1; see Table A-1

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Table 3-2. Special provisions

TIs	*UN*	
. . .		
AXXX		Sterilization devices when containing less than 30 mL per inner gas cartridge with not more than 500 mL per outer packaging of UN 1067 or UN 1660 may be transported on passenger and cargo aircraft in accordance with the provisions in 3;5.1 (excepted quantities), irrespective of the indication “EO” in column 9 of Table 3-1 provided that: Each inner metal gas cartridge must be designed with a safety factor of at least 4 times the working pressure of the receptacle. Each gas cartridge will be packaged with an absorbent material capable of absorbing any leaked material in a sealed compatible plastic bag. Inner packagings must be placed in a rigid outer packaging that meets the packing group I performance standard.
AYYY		Sterilization devices when containing less than 30 mL in inner packagings with not more than 500 mL per outer packaging of Nitric acid (other than red fuming, with more than 20% but less than 65% nitric acid) UN 2031, PG II may be transported on passenger and cargo aircraft in accordance with the provisions in in 3;5.1 (excepted quantities), irrespective of the indication “EO” in column 9 of Table 3-1 provided that: Each inner packaging must be packaged with an absorbent material capable of absorbing any leaked material in a sealed compatible plastic bag. Inner packagings must be placed in a rigid outer packaging that meets the packing group I performance standard.
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APPENDIX B

PORTABLE STERILIZER THAT USES ALTERNATIVE STERILIZATION TECHNOLOGY TO OVERCOME THE LIMITATIONS OF OTHER STERILIZATION METHODS IN LOW-RESOURCE SETTINGS

Overview of the System

The System as depicted in Figure 1 consists of the following:

1. A robust gas cartridge without a release device.
2. A portable, rugged enclosure tested to the PG I performance level.
3. Trays for the placement of the medical instruments to be sterilized that can then be placed in the case.
4. Gas cartridges or ampoules for the transport and introduction of the sterilizing agent into the enclosure.
5. Scrubber/absorbent material for the consumption of the entire gas content in the case of an inadvertent release.
6. A chemical indicator to confirm exposure to the sterilizer gas.

Figure 1. The Portable Sterilizer and its consumables.

Safety Mechanisms

The system employs a safety locking mechanism designed to prevent the exposure of personnel to nitrogen dioxide by:

1. Inhibiting the start of the sterilization cycle until the enclosure is closed.

2. Inhibiting the opening of the case until the sterilization process has completed and the scrubber has absorbed the nitrogen dioxide such that the levels are below the Occupational Health and Safety Administration (OSHA) permissible exposure limits (PEL).

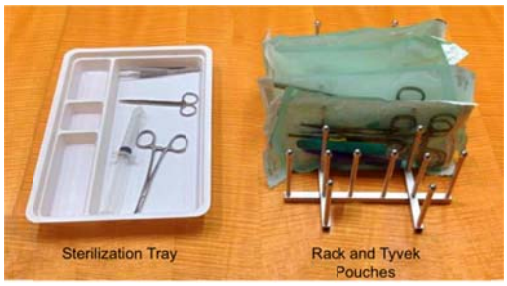

Figure 2. Sterilization options using the Portable Sterilizer.

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