



COMPRESSED GAS ASSOCIATION, INC.

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REAFFIRMED 2006

SAFETY ALERT

4221 WALNEY ROAD, 5TH FLOOR

CHANTILLY, VA 20151

703-788-2700

cga@cganet.com

USE OF NITROGEN NF FOR SURGICAL AIR TOOLS

Two patient-related incidents involving the use of gaseous nitrogen to power operating room surgical instruments or dental office tools have recently been reported to the Compressed Gas Association, Inc. (CGA). These incidents involved the presence of a substance that gave a strong odor to the nitrogen used to power operating suite air tools. In one case a patient in a dentist's office required hospitalization. In both cases the odorizing substance was toxic in nature.

The U.S. Food & Drug Administration (FDA) does not specifically require that nitrogen used to power surgical or dental equipment be listed as either a Medical Device or be Nitrogen NF. However, in light of these two recent incidents and the industry-wide potential for additional similar incidents, the CGA believes that it is appropriate to take a proactive position on this issue. *To that end, the CGA strongly recommends that manufacturers adopt a policy to only sell or distribute Nitrogen NF for the purpose of powering surgical instruments and for any other applications or customers in the health field where the end use application for the gas is unknown.*

This recommendation is being made to protect patient safety. Since medical grade Nitrogen NF production procedures require testing for odor prior to distribution, and industrial, nonmedical grade nitrogen does not, this recommendation will significantly reduce the chance of this type of accident in the future. The majority of manufacturers who distribute nitrogen for these applications are already registered with the FDA and need only add Nitrogen NF to their Drug Listing and adhere to the appropriate current good manufacturing practices (CGMP). If Nitrogen NF is not already a product on the manufacturer's Drug Listing Form, the manufacturer will also need to register and list the product with the FDA, in addition to adhering to CGMP in the receipt, manufacture, testing, release, and distribution of the product.

The CGA believes that this position and recommendation ensures that the industrial gases industry continues to offer safe and effective products to the customers and markets it serves. Additionally, it removes an unnecessary risk to patient health and safety, particularly when viewed in light of the minimal actions required by manufacturers to implement it.

NOTE—The use of nitrogen in enclosed spaces has its own hazards. Please refer to CGA P-39, *Oxygen-Rich Atmospheres* and SB-2, *Oxygen-Deficient Atmospheres*.

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Work Item 05-50
Medical Gases & Equipment Committee

NOTE—No technical information has been changed from the 1998 edition. This reaffirmed edition may include minor editorial changes.

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