STATEMENT ON THE LABELING OF PHARMACEUTICALS FOR USE IN ANESTHESIOLOGY

Committee of Origin: Equipment and Facilities

(Approved by the ASA House of Delegates on October 27, 2004, and last amended on October 21, 2009)

Rationale:

The practice of anesthesiology requires the administration of a wide variety of potent medications. These medications are often given in high acuity situations and in environments with poor visibility and multiple distractions. Medications with widely differing actions, such as muscle relaxants, vasopressors, and vasodilators, are often used in the course of a single anesthetic, at times simultaneously. It has been recognized for some time that perioperative medication errors are a significant source of morbidity and, rarely, mortality.[1-4] Interest in medication errors has extended to regulatory agencies, the federal government, and the general public.

Medications are often selected based upon the location and visual features of the container. The recognition and identification of an object depends on shape, color, brightness, and contrast. As these elements become increasingly distinctive, identification of the object becomes faster and more accurate.[5-7] Identification of the medication is verified by reading the label. Therefore, although multiple factors contribute to medication errors, consistency and clarity of pharmaceutical and syringe labeling, in accordance with human factors, are important elements in their prevention.

References:

1. Currie M, Mackay P, Morgan C, Runciman WB, Russell WJ, Sellen A, Webb RK, Williamson JA. The "wrong drug" problem in anaesthesia: an analysis of 2000 incident reports. *Anaesthesia and Intensive Care.* 1993; 21:596-601.
2. Fasting S, Gisvold SE. Adverse drug errors in anesthesia, and the impact of coloured syringe labels. *Can J Anesth.* 2000; 47:1060-1067.
3. Merry AF, Webster CS. Labeling and drug administration error. *Anaesthesia.* 1996; 51:987-988.
4. *ISO 26825:2008,* Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance.
5. Treisman A. Feature and objects in visual processing. *Scientific American.* November 1986; pp: 114-125.
6. Triesman A. Features and Objects. *Quarterly J of Exp Psychology.* 1988; 40A (vol 2) 201-237.
7. Kosslyn SM. Aspects of a cognitive neuroscience of mental imagery. *Science.* 1988; 240:1621-1626.

***NOTES**: For referenced ASTM International standards, visit the ASTM Web site www.astm.org or contact ASTM customer service at service@astm.org .*

For referenced ISO standards, visit the ISO (International Organization for Standardization) Website at www.iso.org.

STATEMENT ON THE LABELING OF PHARMACEUTICALS FOR USE IN ANESTHESIOLOGY

Statement:

The primary consideration in the design of labels for pharmaceutical containers should be patient safety and the reduction of medication errors. This is particularly true for the potent medications used in the practice of anesthesiology. Therefore, the ASA supports the manufacture and use of pharmaceuticals labels meeting the following standards, which are consistent with those established by American Society for Testing and Materials International (ASTM International) and the International Organization for Standardization (ISO):

1. **Label Content**: The drug's generic name, concentration, and the total volume or contents of the vial or ampoule should be the most prominent items displayed on the label of each vial or ampoule containing pharmaceuticals for use in the practice of anesthesiology. The drug's proprietary name, manufacturer, lot number, date of manufacture, and expiration date should also be included on the label.

2. **Font**: The text on the label should be designed to enhance the legibility, of the drug name and concentration as recommended in ASTM D4267, *Standard Specification for Labels for Small-Volume* (100 ml or less) *Parenteral Drug Containers* and D6398, *Standard Practice to Enhance Identification of Drug Names on Labels*, and *ISO 26825:2008, Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – Colour, design and performance.* These standards include recommendations for font size, extra space for separation around the drug name, and use of additional emphasis for the initial syllable, or a distinctive syllable, of similar drug names.

3. **Contrasting Background**: Maximum contrast between the text and background should be provided by high-contrast color combinations as specified in Section 6.3.1 of ASTM D6398. This minimizes the impact of color blindness:

Text	**Background**
Black	White
Blue	Yellow
White	Blue
Blue	White

4. **Color:** Nine classes of drugs commonly used in the practice of anesthesiology have a standard background color established for user-applied syringe labels by ASTM D4774, *Standard Specifications for User Applied Drug Labels in Anesthesiology* and ISO 26825:2008. For these drugs, the color of the container's top, label border, and any other colored area on the label, excluding the background as required for maximum contrast, should be the color corresponding to the drug's classification. The color would be that established in ASTM D4774 and ISO 26825:2008 and therefore identical to the color of the corresponding syringe label.

STATEMENT ON THE LABELING OF PHARMACEUTICALS FOR USE IN ANESTHESIOLOGY

Drug Class	Pantone Color
Induction Agents	Process Yellow C (RGB 255.255.0)
Benzodiazepines and Tranquilizers	Orange 151 (RGB 255.102.0)
Benzodiazepines Antagonists	Orange 151 (RGB 255.102.0)/White Diagonal Stripes
Muscle Relaxants	Florescent Red 805 (RGB 253.121.86)
Relaxant Antagonists	Florescent Red 805 (RGB 253.121.86)/White diagonal stripes
Narcotics	Blue 297 (RGB 133.199.227)
Narcotic Antagonists	Blue 297 (RGB 133.199.227)/White diagonal stripes
Major Tranquilizers and Anti-Emetics	Salmon 156 (RGB 237.194.130)
Narcotic/Tranquilizer Combinations	Blue 297 (RGB 133.199.227)/Salmon 156 (RGB 237.194.130)
Vasopressors	Violet 256 (RGB 222.191.217)
Hypotensive Agents	Violet 256 (RGB 222.191.217)/White Diagonal Stripes
Local Anesthetics	Gray 401 (RGB 194.184.171)
Anticholinergic Agents	Green 367 (RGB 163.217.99)

5. **Label Enhancements to Reduce Drug Administration Errors:**

- **Bar coding**: Essential information, including the drug's generic name, concentration, and volume of the vial or ampoule should be bar coded at a location on the vial or ampoule which will not interfere with the label's legibility, as specified in Section 8 of ASTM D6398.
- **Peel-off labels** which meet the above criteria for user applied labels and can be transferred directly from the vial to a syringe, along with the contents of the vial, should be added to single-dose vials. These labels reduce the chance of labeling errors and are recommended by Section 3.1 of ISO 26825.2008. Once the peel-off label is removed, the name of the drug shall still be visible on the vial beneath where the peel-off label was removed.
- **Label material** shall allow the user to write information on it using a ball-point pen or felt-tip marker without smudging or blurring as specified in Section 2.3 of ISO 26825:2008.