scientific, and medical (ISM) equipment.''

(8) ''CISPR 16 (1987): CISPR specification for radio interference measuring apparatus and measurement methods.''

(9) ''ANSI C95.3–1991: Recommended practice for the measurement of potentially hazardous electromagnetic fields—RF and microwave.''

(10) ''IEC 68 (1988): Environmental testing.''

(11) ''ANSI/AAMI EC13–1983: Standard for cardiac monitors, heart-rate meters and alarms.'' Copies of this publication may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, suite 1440, Arlington, VA 22201, and may be examined at the Center for Devices and Radiological Health (HFZ–100), 5600 Fishers Lane, Rockville, MD; or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(12) ''MIL–STD–461C (August 4, 1986): Electromagnetic Emissions and Susceptibility Requirements for the Control of Electromagnetic Interference.'' Copies of this publication may be purchased from the Naval Publishing and Printing Service Office, 700 Robbins Ave., Philadelphia, PA 19111–5094, and may be examined at the Center for Devices and Radiological Health (HFZ–100), 5600 Fishers Lane, Rockville, MD; or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(13) ''MIL–STD–462 (July 31, 1967): Standard for the Measurement of Electromagnetic Interference Characteristics.'' Copies of this publication may be purchased from the Naval Publishing and Printing Service Office, 700 Robbins Ave., Philadelphia, PA 19111–5094.

(c) *Precedence of documents.* All referenced documents shall apply to the extent specified herein. When any requirement of this standard conflicts with a requirement in any of the references specified in paragraph (b) of this section, the following rules of precedence shall apply:

(1) *This standard*. This standard shall have precedence over all applicable subsidiary documents specified in paragraph (b) of this section.

(2) *Referenced documents.* Any referenced document shall have precedence over any applicable subsidiary document referenced therein.

§ 896.12 Definitions.

(a) *Apnea* means cessation of respiratory air flow. The respiratory pause may be central or diaphragmatic (i.e., no respiratory effort), obstructive (usually due to upper airway blockage), or mixed (combination of central and obstructive).

(b) *Artifact* means a signal which may be misinterpreted by the monitor; the three most commonly recognized types of artifacts are cardiogenic, electromagnetic, and motion, as defined in paragraphs (d), (g), and (n) of this section.

(c) *Breath* means an inhalation of a volume of at least 2 milliliters of air per kilogram of body weight.

(d) *Cardiogenic artifact* means an artifact produced by theelectrical and/or mechanical activity of the heart.

(e) *Component* means any material, substance, piece, part, or assembly used during device manufacture that is intended to be included in the finished device.

(f) *Damage* means deformation, loosening, breakage, corrosion, change of fit of any component or part, or any other physical condition resulting in nonconformance of the monitor to the requirements of this standard.

(g) *Electromagnetic artifact* means an artifact produced by extraneous electromagnetic energy.

(h) *Finished device* means a device, or any accessory to a device, which is intended for use, whether or not the device is packaged or labeled for commercial distribution.

(i) *Health care practitioner* means a doctor, nurse, therapist, or other health care provider who is licensed by the State or locality in which he/she practices or is credentialed by a nationally recognized agency.

(j) *Infant apnea monitor* means a complete system intended to alarm upon the cessation of breathing and its consequences that is used on humans less than 3 years of age. The infant apnea monitor includes: Sensors; electrodes; leads; cables; tubing; signal processing systems; alarm systems; power supplies; accessories supplied, recommended, or specified by the manufacturer; complete monitoring systems when the apnea function is supplied as a module; and labeling. The terms ''device'' and ''monitor,'' when used in this standard, also mean infant apnea monitor.

(k) *Inspection* means any examination, visual or auditory, performed without the use of special laboratory instruments or procedures and/or verification of manufacturing and test records.

(l) *Intended* means the same as ''intended uses as specified by the manufacturer.''

(m) *Monitor* means an infant apnea monitor.

(n) *Motion artifact* means an artifact produced by movement of the patient.

(o) *Operator* means the individual who applies the infant apnea monitor to the patient, or who monitors the patient and the functioning of the device. The term ''operator'' includes individuals, such as parents, nurses, therapists, care givers, etc., but does not include business entities, such as hospitals, corporations, partnerships, etc.

(p) *Operator maintenance* means performance by the operator or health care practitioner of those adjustments or procedures specified in the operator or health care practitioner information provided by the manufacturer for the purpose of assuring the continued safe and effective performance of the monitor.

(q) *Patient* means the individual being monitored by the infant apnea monitor.

(r) *Primary monitoring modality* means a method for detecting the cessation of breathing (apnea).

(s) *Secondary monitoring modality* means a method that measures, on a continuous basis, a physiological parameter that responds to the pathophysiological consequences of apnea, such as bradycardia, hypoxemia, or hypercarbia (hypercapnia).

(t) *Service* means performance of the procedures or adjustments described in the manufacturer's service instructions that may affect any aspect of the performance of the infant apnea monitor to which this standard applies.

(u) *Shall* means that a provision is mandatory.

(v) *Should* means that a provision is recommended.

(w) *Status indicator* means a device subsystem that shows, in a timely manner, either the status or condition of a physiological parameter of the patient or a particular characteristic of the device.

Subpart B—Patient Monitoring Requirements

§ 896.20 Primary monitoring modality.

Each monitor shall provide:

(a) A primary monitoring modality which shall incorporate a means for detecting the cessation of breathing or of breathing effort (apnea). The manufacturer shall specify the types of apnea that the primary monitoring modality will detect.

(b) A timer to measure apnea duration, and a system of visual and audible warning status indicators designed to activate (alarm) when the measured apnea duration is greater than the preset time, which shall not exceed 20 seconds. The indicators shall be activated within 1 second after the preset time is exceeded in accordance