wire and cable design, whether or not the device was intended for home use. Despite these efforts, some hospitals continue to use older units, or electrode lead wires and patient cables from other devices, which do not have the protective electrode lead wire and cable design. Even with the new models, as evidenced by the 1993 incident, it may be possible to switch patient cables and/or electrode lead wires, thereby creating a hazard.

On September 3, 1993, FDA issued a safety alert to hospital administrators, risk managers, and pediatric department directors, warning them that the use of unprotected electrode lead wires with an apnea monitor may be dangerous to the patient, and may be in violation of section 518(a) of the act (21 U.S.C. 360h(a)) (Ref. 4). FDA included in the alert a number of recommendations to help prevent these accidents. FDA also sent all apnea monitor manufacturers a notification letter under section 518(a) of the act (Ref. 5).

Section 518(a) of the act authorizes the agency to issue an order to assure that adequate notification is provided in an appropriate form, by the means best suited under the circumstances involved, to all health professionals who prescribe or use a particular device and to any other person who should properly receive such notification, in order to eliminate an unreasonable and substantial harm to the public health when no other practicable means is available under the act to eliminate such risk. FDA stated that, for these devices, notification should include replacement of unprotected electrode lead wires and patient cables, and that a warning label should be permanently affixed to all monitors stating that unprotected electrode lead wires and patient cables should not be used with the device because inappropriate electrical connections may pose an unreasonable risk of adverse health consequences or death. FDA also requested manufacturers of all apnea monitors to cease further distribution of unprotected electrode lead wires and patient cables. On September 20, 1993, FDA issued a similar letter to all known third-party manufacturers of patient cables and electrode lead wires (Ref. 6).

On December 28, 1993, FDA issued a Public Health Advisory to hospital nursing directors, risk managers, and biomedical/clinical engineering departments for distribution to all units in their hospitals and outpatient clinics, as well as to home health care providers and suppliers affiliated with those facilities, advising them of the hazards associated with use of electrode lead wires with unprotected male connector pins (Ref. 7). In the Public Health Advisory, FDA expanded the scope of its September 3, 1993, apnea monitor safety alert to include all devices using patient electrodes. FDA noted that, even though manufacturers have changed the design of their devices to minimize the potential hazard, some facilities are still using older models that make it possible for staff to switch patient cables and/or lead wires, thus creating a hazard. FDA recommended various precautions to prevent the use of unsafe lead wires and patient cables.

Manufacturers of devices other than apnea monitors that utilize patient electrodes, e.g., ECG, have been encouraged by various organizations to modify their electrode lead wires so that they cannot be inserted into AC power cords or outlets. For example, in February 1987 and May 1993, ECRI issued hazard reports concerning electrical shock hazards from unprotected electrode lead wires and patient cables. Further, standards-setting bodies have developed various standards, both in draft and final form, that have the same goal in mind—safety requirements for patient electrode lead wires.

IEC has proposed an amendment to IEC 601–1, the safety standard for electromedical equipment, requiring that electrode lead wires be unable to make contact with hazardous voltages. This amendment was approved and published in March 1995.

The Underwriters Laboratories (UL) adopted IEC 601–1 by issuing its standard 2601–1. It became effective on August 31, 1994. This standard supersedes UL 544 (referenced in the ANPRM). In adopting the IEC standard, UL included a deviation that requires that patient electrodes be designed to avoid connection to electrical power sources. (See UL 2601–1, Medical Electrical Equipment Part 1: General Requirements for Safety.) The UL standard states in the rationale section that ''this is a basic safety concern prompted by recent accidents involving patient injury, including infant deaths. Patients were accidently being connected to hazardous circuits while being connected to applied parts of medical equipment, such as an apnea monitor.'' FDA has been advised that it is possible that UL will modify its requirement to be equivalent to the one included in the proposed amendment to IEC 601–1.

There is also a German DIN standard for touch proof connectors for electromedical applications. This design standard was also referenced in the ANPRM and states that it was developed because of the accidents that occurred with infants in 1985 and 1986.

The National Fire Protection Agency (NFPA) is also proposing a standard for patient electrode lead connectors. FDA has received information that even though it is voluntary, this NFPA standard will be adopted by many States and municipalities as a mandatory standard for health care facilities. Further, this standard is referenced by the Joint Commission on Health Care Organizations.

Finally, the Association for the Advancement of Medical Instrumentation (AAMI) is developing a standard that covers cables and patient lead wires for surface electrocardiographic monitoring in cardiac monitors applications. The draft standard addresses safety and performance of cables and lead wires with the added purpose of encouraging the availability of lead wires that are interchangeable for ECG monitoring applications. The standard defines a safe (no exposed metal pins) common interface at the cable yoke and lead wire connector. The draft standard is currently being balloted by AAMI and undergoing public review for acceptance as an American National Standard.

FDA believes that industry also recognizes the importance of addressing this hazard. In response to FDA's alert letter in June 1985, manufacturers voluntarily began to redesign their electrode lead wires and patient cables for home apnea monitors. And more recently, many firms have taken voluntary action to recall electrode lead wires with unprotected exposed metal pins and/or unprotected patient cables. Apnea monitor firms are replacing their male pin lead wires and associated cables with safety cable systems, usually free of charge, while others are making adapters and warning labels available. Some device manufacturers have ceased supplying unprotected electrode lead wires.

II. Highlights of the Proposal

This rule proposes to establish a performance standard that FDA believes will eliminate the risk of electrode lead wires being inserted or otherwise manipulated so as to make contact with live parts of a power outlet or separable power cord. This standard would apply to all medical devices that use patient-connected electrode lead wires.

FDA is proposing a 1- or 3-year effective date for any final regulation based on this proposed promulgation of a performance standard. Devices that would be subject to the 1-year effective date are those devices that present the