greatest potential risk of harm as demonstrated by use in environments where accidental inappropriate connections could reasonably be anticipated, and by frequent use of the devices and frequent connections of electrode lead wires. Devices subject to the 1-year effective date would also include devices that have been the subject of reported adverse events, and those that can be reasonably anticipated to be the subject of adverse events. Devices that would be subject to the 3-year effective date are those devices that do not satisfy the criteria for the 1-year effective date but also utilize unprotected electrode lead wires. The agency is also proposing to ban devices that do not meet the standard on its effective date.

III. The New Framework

As noted in the ANPRM, FDA recognizes that despite the many efforts described above, the potential risks presented by the continued use of unprotected electrode lead wires and patient cabling systems still exist. In order to eliminate these risks completely, the agency is proposing to establish a performance standard that would apply to all medical devices that use patient-connected electrode lead wires.

In reaching this decision, the agency reviewed several standards that are in various stages of development before deciding to propose to establish its own. FDA decided not to adopt these standards for this proposal because some of them were too restrictive or not restrictive enough for application to all devices. In addition, it would cause unnecessary delay in FDA's handling of this matter to obtain the appropriate clearances for the adoption of an existing standard. FDA believes, however, that devices that meet the IEC, AAMI, and NFPA standards for protected electrode lead wire and cable configurations would also meet FDA's proposed standard.

The agency believes that firms whose devices would be subject to the proposed performance standard will begin adapting existing products to the standard, or modify ''new devices'' to conform them to the standard, if they have not already done so, before the effective date of the standard. This would be consistent with Congress' admonition that ''stockpiling of nonconforming devices is discouraged, since standards will apply to all devices in commercial channels on their effective date.'' (See H. Rept. 853, 94th Cong., 2d sess. 30; see also 45 FR 7474, February 1, 1980, final standards regulations.)

FDA is publishing a list of devices utilizing patient contacting electrodes that would be subject to the 1- or 3-year phase-in process of the performance standard. FDA reserves the right, upon proper notification to interested parties, to amend this list at any time. FDA believes the proposed effective dates are reasonable and consistent with the congressional intent in enacting section 514 of the act, as well as with comments at the public conference.

To ensure a full adherence to the standard by both new and existing products in commercial distribution and use, the agency is also proposing to ban all devices that do not meet the standard on its effective date.

IV. Performance Standard

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) prescribes changes to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321–394), as amended, that improve the regulation of medical devices and strengthen the Medical Device Amendments of 1976 (the 1976 amendments), which established a comprehensive framework for the regulation of medical devices.

The SMDA amended section 513 of the act (21 U.S.C. 360c) to redefine class II as the class of devices that is or will be subject to special controls, and amended section 514 of the act (21 U.S.C. 360d) to simplify the requirements for establishing performance standards. Section 513 of the act states that the ''special controls * * * shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.'' The legislative history of the SMDA states that:

> by simplifying the process for establishing performance standards, and by allowing the Secretary discretion to employ such standards as one of a variety of additional controls to assure the safety and effectiveness of Class II devices, performance standards will become valuable tools to regulate those devices for which they are most needed.

(S. Rept. 513, 101st Cong., 2d sess. 19 (1990).)

Under this proposal, this mandatory standard would apply to all electrode lead wires, and would be phased-in over a period of 3 years. Proposed § 897.12(a) and (b) contain lists of devices that would be subject to the performance standard, with the applicable effective dates of the standard.

A. The Proposed Standard

FDA proposes the following mandatory performance standard for patient-connected electrode lead wires. Any lead wire intended to provide electrical contact between a patient and any medical device shall be protected such that the connector at the lead wire end that is distal to the patient cannot make conductive contact with an AC electrical power source (e.g., wall receptacle, power cord plug).

B. Findings

Unprotected electrode lead wires and patient cabling systems have been associated with burns and electrocutions. The fact that these injuries and deaths occurred in both homes and hospitals emphasizes the need to address this problem on a wider scale. Until all unprotected electrode lead wires and patient cables are out of the user environment, the potential hazard exists. FDA believes that a proactive approach warranted to address this potential hazard adequately.

Despite repeated efforts to eliminate the serious hazard they pose, the production and use of unprotected electrode lead wires continue. Although many firms are taking corrective action, others continue to supply users with unprotected electrode lead wires, and users continue to request and use them. Therefore, to eliminate the serious risks to health presented by these devices, FDA is proposing that all devices featuring patient connected electrode lead wires be redesigned or adapted to prevent the risk by the end of a 3-year period.

C. Opportunity to Request a Change in Classification

In accordance with section 514(b)(1)(B)(iii) of the act and § 860.132, FDA is offering interested persons an opportunity to request a change in the classification of any device that would be subject to the proposed standard, based on new information relevant to its classification. Any proceeding to reclassify a device will be in accordance with section 513(e) of the act.

A request for a change in the classification of a device that uses electrode lead wires is to be in the form of a reclassification petition containing information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 514(b)(1)(B) of the act, be submitted before July 21, 1995.

The agency advises that, to ensure timely filing of any such petition, any