device is retrofitted by an adapter and, in some cases, redesigned by the original equipment manufacturer. Several other comments noted that diagnostic instruments cannot accept redesigned electrode connections without modifying the device.

FDA believes that if devices cannot accept safety lead sets currently available, modifications can be made to the design of the lead, and may also be necessary for the device with which the lead is intended to be used. Indeed, one comment noted that modification kits will be available to permit the use of protected electrode lead wires on certain devices that currently cannot accept them.

As noted at the conference, the electrode lead wires for TENS, Holter, and other event monitors may migrate into other clinical areas. Indeed, FDA believes that the same is true for all electrode lead wires, including those intended for diagnostic use. Therefore, FDA is proposing that all unprotected electrode lead wires be redesigned or adapted to prevent the risk to health presented by these devices.

It should be noted that certain battery powered devices (e.g., Holter monitors, TENS, biofeedback devices) are proposed for Phase 1 implementation. If battery powered, these devices do not pose a direct electrical hazard. However, FDA is concerned about their unsupervised use outside a clinical setting, and the potential hazard presented when their pin-style electrode lead wires are connected to a patient instead of to a device. Based on previous adverse experiences with home-use apnea monitors, FDA believes it prudent to require early conversion of these other home-use devices, and is proposing to include them in Phase 1.

9. A trade association stated that it is not aware of any device that inherently cannot accept a redesigned, protected electrode lead. As noted in response to the comment above, FDA believes that if current devices cannot accept safety lead sets currently available, modifications can be made to the design of the lead, and may also be necessary for the device with which the lead is intended to be used. Indeed, one comment noted that modification kits will be available to permit the use of protected electrode lead wires on certain devices that currently cannot accept them.

10. Some hospitals and other providers contended that immediately replacing devices or parts would be too costly and logistically difficult. One comment stated that the cost of converting to protected electrode lead wires and patient cables would increase the costs of medical care. In contrast, one comment stated that the conversion cost to health care providers would not be unreasonably high given the potential loss of life if unprotected electrode lead wires continue to remain available. A few user facilities noted that unprotected electrode lead wires are not only less expensive than protected electrode leads, but they also have several additional advantages for hospitals, i.e., light in weight, and a standard size and shape (allowing the hospital to use the wires for multiple purposes). These facilities believe that the unprotected electrode lead wire problem will resolve itself in time because, as replacements are needed, safer leads will be ordered.

FDA believes that a long-term ''natural'' phaseout is an unacceptable solution to the problem. Indeed, one manufacturer of electrode lead wires reported that it continues to fill requests for unprotected lead wires, and does not anticipate any decrease in such requests. One comment estimated that 1.5 million unprotected electrode lead wires and patient cables are manufactured and distributed annually in the United States either for new use or as replacement products, and 10 to 40 million unprotected electrode lead wires and patient cables are currently in circulation. Moreover, FDA believes that any ''natural'' phaseout that might occur, would take much longer than is reasonable and necessary. FDA believes that a proactive approach is necessary to address this potential hazard adequately. Therefore, to eliminate the serious risks to health presented by these devices, FDA is proposing that all devices featuring patient-connected unprotected lead wires be redesigned or adapted in order to eliminate the risk by the end of a 3-year period.

11. A few comments stated that the cost of converting unsafe cables to safe cables is manageable. One comment noted that the manufacturing of electrode lead wires with protected pins, such as pins meeting DIN 42 802, costs only a few cents more than manufacturing lead wires with unprotected pins. In addition, this comment continued, the cost of the jacks that fit into the equipment is also consistent with the costs of the 2-millimeter pin jack. This comment concluded that any additional costs for new equipment are not significant compared to the cost of retrofitting equipment in the field. This comment believed that retrofitting would require significant changes to cases and printed circuit boards, and is not warranted in light of the frequency and nature of the accidents that have occurred.

FDA believes that the cost of converting or adapting unsafe electrode lead wire configurations to safe electrode lead wire configurations meeting its proposed standard is manageable because the agency will be phasing in its standard over a 1- to 3-year period. Furthermore, FDA believes that this cost is justifiable given the nature of the adverse events reported and those that may be reasonably anticipated if these devices were to remain available.

12. Several comments noted that the cost of converting to protected electrode lead wires will be greater for devices that will have to be completely redesigned to accommodate safe connections when electrode lead wires are directly inserted into them.

As noted above, FDA believes that this cost is justifiable and will be manageable given the availability of permanent adapter blocks and the range of time FDA is proposing for adherence to the standard.

13. One comment noted that the likelihood that nonmedical electrode lead wires and patient cables would be substituted for medical uses is virtually nonexistent. Another comment noted that no data are available indicating the extent of such substitution.

FDA has seen no data describing the extent of substitution of nonmedical electrode lead wires and patient cables for protected medical electrode lead wires and patient cables.

14. Some manufacturers claimed that substitution of unprotected electrode lead wires and patient cables can be avoided if the equipment is used properly and adequate warnings and instructions are provided with all devices. On the other hand, some users claimed that the reason why electrode lead wires and patient cables are misused is the poor design of the devices.

Although FDA recognizes that user education and training are essential to the proper use of all devices, including unprotected electrode lead wires, a variety of additional factors are involved when improper electrical connections are made. One of these factors is the cognitive ability of the operator, e.g., sibling, caregiver, or parent, at the time of an incident, and another factor is the environment in which the device is being used. It is worth noting that, in the Chicago hospital incident discussed earlier, the health care professional had 8 years of prior experience. Therefore, FDA believes that the most effective solution to the unprotected electrode lead wire problem is a change in the design of the device.