15. Several comments stated that there is a need for electrical safety education specific to patient cables and electrode lead wires for all personnel who come in contact with them in the patient care setting.

FDA agrees with this comment.

16. Several comments stated that there are certain areas of a hospital that present a higher risk than others for inappropriate electrical connections. These comments mentioned intensive care units (ICU's), cardiac care units (CCU's), and emergency rooms as examples of high risk areas because many times people in those areas are under stress or fatigued, and events are happening extremely quickly. Another comment noted that what was clear regarding reported deaths and macro-shocks from unprotected electrode lead wires was that there were no known reports involving adults. Therefore, this comment continued, the obvious conclusion is that neonatal ICU's, nurseries, and pediatric units where infants are cared for in a hospital should be the first priority in terms of engineering controls and education. The next areas that should be focused on are ICU's, CCU's, and possibly operating rooms. Finally, the comment concluded, areas using diagnostic devices clearly should be addressed last because of the expense of conversion and the unique attributes of that environment, including the fact that operators are trained, there are very few transactions, things are done in a linear fashion, and there is no risk of improper connections by parents, which was the cause of some of the reported incidents. A trade association added that, in any procedure-based area in a hospital, e.g., the catheter lab, the probability of a problem occurring with a single bare-pin lead electrode and a female end of a power cord is diminished.

FDA has considered the environments where these devices are used, the frequency with which they are used and the reported and reasonably anticipated potential adverse events in determining whether specific devices should be subject to either the 1- or the 3-year effective date of the standard.

FDA believes that, even though current law requires that hospitals and other users of medical devices report serious injuries and deaths, there probably has been underreporting of deaths and serious injuries caused by unprotected patient electrode lead wires. FDA believes that most of the deaths, particularly those involving infants, probably have been reported to FDA. However, the agency believes that some injuries, that could be related to these devices, including serious injuries, probably have not been reported.

17. Many comments stated that the risk analysis and the history of incidents involving ECG and apnea monitoring equipment support a need for a performance standard for these devices. One comment at the conference noted that intraoperative EEG monitoring equipment should be included in any FDA regulatory action because the leads used with this equipment are similar to those used with the ECG and apnea monitoring.

FDA believes that all unprotected electrode lead wires present a risk for patients connected to them and, therefore, would be subject to the proposed performance standard and ban.

18. One comment suggested that new devices should be required to have a permanently wired cord. In contrast, another comment noted that hardwiring the modular power cord to the equipment is a poor alternative in light of the costs and logistical feasibility of this action. The modular power cord, this comment continued, is inherently safe and is a standard across the entire industry base. This comment believes that the problem is not the power cords, but rather the lead wires and the lack of training of the individuals using them.

FDA believes that hardwiring the power cord to the monitor is not a solution to the hazard presented by an exposed male pin. FDA's proposed actions, therefore, focus on the unprotected electrode lead wire, where an inappropriate connection can be made.

19. One comment recommended changing the ECG monitoring color codes for lead placement to avoid duplication with those used for the power cord.

FDA believes that a color change is not the most appropriate and direct solution to the problem. As noted above, several factors play a role in an improper connection.

20. During the conference it was stated that the detached power cord was the primary source for all of the incidents involving macro-shocks and deaths associated with unprotected lead wires. Furthermore, it was noted that there have been no accidents in the home, resulting in either injuries or deaths, since 1987. All of the accidents that have occurred since then have occurred in a hospital setting.

As noted in comment 18, FDA believes that the characteristics of the power cord can not eliminate the hazard presented by an exposed male pin. Therefore, FDA's proposed actions focus on the unprotected electrode lead wires. Since 1985, unprotected electrode lead wires have been associated with burns and electrocutions in both homes and hospitals. Therefore, FDA does not believe that the focus of its proposed actions should be limited to a specific environment. FDA has considered the intended environments of use, however, in determining when the proposed requirements would be applicable to a particular device.

21. Several comments objected to the notion that one standard could be appropriate for electrode lead wires and patient cables used in multiple diagnostic procedures because the performance attributes are different.

FDA believes that the proposed standard provides enough flexibility for manufacturers to design safety leads that take into account the type of diagnostic procedure involved, the physical characteristics of each examination and operating room, as well as each physician's or technician's personal preference for use of the diagnostic instrument on the patient. Hence, FDA has determined that one performance standard would be appropriate for all electrode types.

22. Several comments recommended that a risk-based assessment of the unprotected electrode lead problem should be a component of any FDA action. Devices that present the greatest risk should be given the greatest attention.

FDA has determined that all devices that use electrode lead wires should be subject to the proposed performance standard and ban. However, FDA has decided to phase-in its proposed requirements to allow sufficient flexibility for all devices that use unprotected electrode lead wires to be converted. As noted in the response to comment 20, FDA considered risk in determining when the proposed requirements would be applicable to a particular device.

23. One comment stated that lead wire connectors should not have exposed metal that can be connected to a ground or power source, either foreign or domestic.

FDA agrees. Therefore, its proposed standard attempts to achieve this goal.

24. Several comments stated that a performance standard should be focused on line-powered devices and, even more specifically, on apnea monitoring and ECG devices, for which there have been reported adverse incidents. One comment added that other devices should not be required to change to protected electrode lead wires until they are shown to present a risk to patients.

FDA is proposing to apply its standard to all devices featuring