''Rationale for Requirements—Infant Apnea Monitor Standard'' (Ref. 3) provides a rationale for each of the requirements contained in the standard and an associated bibliography. In developing the proposed standard, FDA has made extensive use of existing international standards, particularly the International Electrotechnical Commission standards. A section on definitions is intended to provide precise meanings for terms used in the proposed regulation.

The section on patient monitoring includes the requirement that each infant apnea monitor system contain a secondary monitoring modality. The purpose of this requirement is to increase the likelihood that the monitor will detect apneic events. Visual and audible alarms (status indicators) are required, as is the availability of a remote alarm unit for monitors intended for home use. In order to alert the care giver to any malfunction before using the device, a self test requirement is included.

The electrical requirements for infant apnea monitors include requirements for battery backup, operation from an ungrounded power source, and limitation of leakage current. An extensive set of requirements is provided to ensure electromagnetic compatibility of infant apnea monitors, which can be a serious device problem. Given the complexity of certain testing for these devices, FDA has prepared a document entitled: ''Additional Guidance for Testing Immunity to Radiated Electromagnetic Fields—Infant Apnea Monitor Standard'' (Ref. 2), which provides manufacturers some assistance in conducting immunity testing.

The mechanical and environmental requirements mandate tamper proof controls, protection against misconnection of wires and tubing, and the ability to withstand normal shock, vibration, temperature extremes, and fluid spills.

The labeling requirements specify information to be provided by the manufacturer to both operators and health care practitioners, and include specific device labeling requirements.

Recommended test procedures (Ref. 1) are included for each requirement in the standard. These procedures are referee test methods, i.e., they are the methods FDA will use to verify that a specific apnea monitor meets the requirements of the standard. Manufacturers are required, after the effective date of the standard, to meet the requirements of the standard. However, manufacturers may choose to use alternative but equivalent or better test methods for each monitor or, in lieu of individual testing, an analysis for a specific production run of monitors or, in lieu of any specific testing, an analysis which shows that each device meets the requirements of the standard.

The ''Rationale for Requirements—Infant Apnea Monitor Standard'' (Ref. 3) contains a detailed rationale for each requirement in the proposed standard.

Accordingly, the agency is proposing to add new part 896, to the Code of Federal Regulations, to establish a mandatory performance standard for the infant apnea monitor.

Additional guidance for the tests used to determine the immunity of monitors to radiated electromagnetic fields is provided in a separate document (Ref. 2).

III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impactstatement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency has concluded that the proposed rule will have a minimal impact on manufacturers of infant apnea monitors. A copy of this analysis is on file in the Dockets Management Branch (address above).

The proposed rule will require that manufacturers comply with performance requirements in four major areas: Patient monitoring, electrical characteristics, mechanical and environmental characteristics, and labeling. This is a set of minimal requirements based on existing technologies. Additionally, the proposed rule will not become effective for 1 year after it is issued in final form. Current manufacturers will have ample time to meet these minimum standards as part of a normal cycle of product improvement and development. Therefore, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities and, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1980

This proposed rule contains information collections which have been reviewed by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and approved under control no. 0910–0073. The title, description, and respondents of the information collections are shown below with the annual recordkeeping burden.

Title: Standard for the Infant Apnea Monitor.

Description: The standard describes basic performance features, and labeling information, for infant apnea monitors which are intended for hospital and/or home use. The monitor shall be a complete system, suitable for its intended purpose of accurately and reliably providing alarms as needed to the caregiver.

Description of Respondents: Manufacturers of apnea monitors. The burden of 360 hours for recordkeeping concerning the design of, and rationale for, the tests used to meet this standard, together with analysis and results of the tests is approved under the OMB information collection 0910–0073. The annual burden for recordkeeping is as follows: