body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current.

It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air)

Issued in Washington, DC on August 15, 1995.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC,

PART 95—[AMENDED]

1. The authority citation for part 95 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

2. Part 95 is amended to read as follows:

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES AND CHANGEOVER POINTS

[Amendment 391 Effective Date, September 14, 1995]

From	To	MEA
§ 95.6026 VOR Federal Airway 26 Is Amended To Read in Part		
Huron, SD VORTAC *3200—MOCA	Obitt, SD FIX	*4000
§ 95.6033 VOR Federal Airway 33 Is Amended To Read in Part		
Faged, VA FIX	Colin, VA FIX	4000
§ 95.6181 VOR Federal Airway 181 Is Amended To Read in Part		
Sioux Falls, SD VORTAC *3300—MOCA	Obitt, SD FIX	*4000
Obitt, SD FIX *3100—MOCA	Watertown, SD VORTAC	*4000
§ 95.6220 VOR Federal Airway 220 Is Amended To Read in Part		
Sioux Falls, SD VORTAC *3200—MOCA	Watertown, SD VORTAC	*4000

From	To	MEA	MAA
§ 95.7505 Jet Route No. 505 Is Amended To Read in Part			
Seattle, WA VORTAC	U.S. Canadian Border	#24000	45000

#MEA is established with a gap in navigation signal coverage.

Airway segment		Changeover points	
From	To	Distance	From
§ 95.8005 Jet Routes Changeover Points. Is Amended by Adding			
Seattle, WA VORTAC	Cranbrook, Canada VOR/DME	108	Seattle.

[FR Doc. 95–21015 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 97

[Docket No. 28298; Amdt. No. 1679]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents,

U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Navigation (air).

Issued in Washington, DC on August 11, 1995.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

*** * * Effective September 14, 1995**

Searcy, AR, Searcy Muni, NDB OR GPS RWY 1, Amdt 3
Sacramento, CA, Sacramento Metropolitan, ILS RWY 16L, Orig
Jacksonville, FL, Craig Muni, ILS RWY 32, Amdt 3
Meade, KS, Meade Muni, NDB RWY 17, Amdt 1, CANCELLED
Odenton, MD, Col. William F. (Shorty) Tipton, NDB or GPS RWY 10, Orig
Marquette, MI, Marquette County, ILS RWY 8, Amdt 10
Marquette, MI, Marquette County, LOC BC RWY 26, Amdt 9
Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 15, Amdt 3
Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 33, Amdt 4
Rice Lake, WI, Rice Lake Muni, NDB RWY 36, Amdt 7, CANCELLED
Rice Lake, WI, Rice Lake Muni, VOR or GPS RWY 36, Amdt 1, CANCELLED
Rice Lake, WI, Rice Lake Muni, VOR or GPS RWY 18, Amdt 1, CANCELLED
Rice Lake, WI, Rice Lake Regional—Carl's Field, NDB RWY 19, Orig

*** * * Effective October 12, 1995**

Dunnellon, FL, Dunnellon, VOR/DME RWY 23, Amdt 1
Sandpoint, ID, Dave Wall Field, LOC/DME–A, Orig
Sandpoint, ID, Dave Wall Field, NDB/DME–C, Orig
Coatsville, PA, Chester County G. O. Carlson, ILS RWY 29, Amdt 6
Langhorne, PA, Buehl Field, VOR RWY 6, Amdt 6A, CANCELLED

*** * * Effective November 9, 1995**

Grants Pass, OR, Grants Pass, GPS–A, Orig
Lakeview, OR, Lake County, GPS RWY 34, Orig
Laredo, TX, Laredo Intl, VOR/DME OR TACAN OR GPS RWY 14, Amdt 9
Laredo, TX, Laredo Intl, LOC BC RWY 35L, Amdt 1
Friday Harbor, WA, Friday Harbor, GPS RWY 34, Orig

Note: Portland, OR, Portland Intl, LOC BC RWY 10L, AMDT 14, published in TL 95–15 with a cancellation date of 20 JUL 95 is rescinded. The LOC BC RWY 10L, Amdt 14 will remain in effect until further notice.

Note: Reference TL95–14 dated June 16, 1995 . . . The following procedures were mentioned in the index but not included in the transmittal package:
Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 15, Amdt 3

Cleburne, TX, Cleburne Muni, VOR/DME RNAV OR GPS RWY 33, Amdt 4

Note: The FAA published an Amendment in Docket No. 28286, Amdt No. 1677 to Part 97 of the Federal Aviation Regulations (VOL 60 FR No. 151 Page 40071; dated Monday August 7, 1995) under Section 97.23 effective 14 SEP 95 which is hereby amended as follows:

Jacksonville, FL. Craig Muni, should read VOR or GPS Rwy 32, Amdt 2, CANCELLED

Note: The FAA published an Amendment in Docket No. 28266, Amdt No. 1674 to Part 97 of the Federal Aviation Regulations (VOL 60 FR No. 136 Page 36349; dated Monday July 17, 1995) under Section 97.27 effective 14 SEP 95, which is hereby amended as follows:

Loris, SC. Twin City, should read NDB or GPS Rwy 26, Amdt 2, CANCELLED

[FR Doc. 95–21014 Filed 8–23–95; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 93N–0027]

Neurological Devices; Effective Date of Requirement for Premarket Approval of Cranial Electrotherapy Stimulators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the cranial electrotherapy stimulator (CES), a medical device. This action is being taken under the Medical Devices Amendments Act of 1976. Commercial distribution of this device must cease, unless a manufacturer or importer has filed with FDA a PMA for its version of the cranial electrotherapy stimulator device within 90 days of the effective date of this regulation.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Janine M. Morris, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 4, 1979 (44 FR 51770), FDA published § 882.5800 (21 CFR 882.5800) classifying the CES into class III (premarket approval). Section 882.5800 applies to (1) Any CES that was in commercial distribution before May 28, 1976, the date of enactment of the Medical Devices Amendments of 1976 (the amendments) (Pub. L. 94–295), and (2) any device that FDA has found to be substantially equivalent to the CES and that has been marketed on or after May 28, 1976.

In the **Federal Register** of August 31, 1993 (58 FR 45865), FDA published a proposed rule to require the filing under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)) of a PMA or a notice of completion of a PDP for the CES. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the evice to meet the premarket approval requirements of the act, and the benefits to the public from use of the device (58 FR 45865 at 45867). The August 31, 1993, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act (21 U.S.C. 360e(b)(2)(B)), FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the cranial electrotherapy stimulator was required to be submitted by September 15, 1993. The comment period closed on November 1, 1993.

FDA received two petitions requesting a change in the classification of the device from class III to class II. FDA reviewed the petitions and found them deficient based on the lack of new information that was relevant to the device's classification. Each petitioner was sent a deficiency letter dated February 4, 1994, requiring a response to the reported deficiencies. Both petitions were deemed closed August 23, 1994, based on the petitioners' lack of response.

II. Summary and Analysis of Comments and FDA's Response

The comments addressed issues relating to valid scientific studies pertaining to behavioral science and risks associated with the use of the CES device. (See 58 FR 46865 at 46867 and 46868 for a discussion of the benefits and risks of the CES device.) The comments are summarized as follows:

1. A few comments were concerned that FDA's proposed findings were not evaluated by qualified behavioral scientists who could read and understand the literature. The comments noted that several references cited in the proposal do not meet the behavioral science criteria of a reliable ''dependent vector'' and would not have appeared in a knowledgeable behavioral science review. The comments further noted that the review conducted by a National Research Council panel on Electrosleep and Electroanesthesia did not include any behavioral scientists, and 90 percent of the studies reviewed by the panel were behavioral science studies.

FDA recognizes that the proposed rule did not present critical reviews of all the literature. FDA also agrees that many of the studies in the literature do not meet the minimum criteria of behavioral science review. FDA has cited these publications only to show that the valid scientific evidence that is required to demonstrate the safety and effectiveness of CES devices in the form of well-controlled clinical studies is not presented in published data. FDA believes the data presented in the literature are not sufficient to fulfill the requirements of valid scientific evidence. Some of the studies were controlled studies that may have indicated some effect; however, information in the literature does provide a reasonable assurance that the device produces a reliable, repeated treatment effect. The few studies that presented controlled data were studying different clinical endpoints on a small number of patients so that an effect could not be established.

2. One comment said that the risks to health identified in the proposed rule (worsening of the condition being treated, potential risk of seizure, skin irritation, and blurred vision) appear exaggerated, as discussed below:

a. The comments said the risk of worsening of the condition being treated could easily be controlled by informing the patient when he or she should expect the treatment effect to occur. The comments stated that, for the case of a depressed patient, the perceived worsening effect is due to the patient's expectations for immediate effect.

FDA agrees that the risk of worsening of the condition being treated might be controlled. However, until the CES is proved effective through valid scientific evidence, the agency believes that patients should not be subjected to the risk of worsening their condition by an ineffective treatment.

b. One individual commented on personal involvement in a number of studies comprising a total of 800 patients where 26 of the patients were