FDC date	State	City	Airport	FDC No.	SIAP
01/10/00	OH	Mansfield	Mansfield Lahm Muni	0/0266	ILS Rwy 32, Amdt 15A...
01/10/00	OH	Mansfield	Mansfield Lahm Muni	0/0267	VOR or GPS Rwy 32, Amdt 6...
01/10/00	OH	Mansfield	Mansfield Lahm Muni	0/0268	VOR or GPS Rwy 14, Amdt 13...
01/10/00	OH	Portsmouth	Greater Portsmouth Regional	0/0244	VOR/DME RNAV or GPS Rwy 18, Amdt 6A...
01/10/00	OK	Lawton	Lawton-Fort Sill Regional	0/0240	RADAR–1, Amdt 4...
01/11/00	MO	Springfield	Springfield-Branson Regional	0/0288	VOR or Tacan Rwy 20, Amdt 18...
01/11/00	TX	Brownsville	Brownsville/South Parde Island Intl.	0/0300	ILS Rwy 13R, Amdt 11A...
01/11/00	TX	Brownsville	Brownsville/South Parde Island Intl.	0/0301	LOC BC Rwy 31L, Amdt 11...
01/12/00	AK	Barrow	Wiley Post-Will Rogers Memorial.	0/0345	GPS Rwy 24, Orig...
01/12/00	MN	Thief River Falls	Thief River Falls Regional	0/0325	VOR/DME Rwy 31, Amdt 3A...
01/12/00	OH	Cincinnati	Cincinnati Muni—Lunken Field.	0/0326	NDB or GPS Rwy 25, Amdt 8...
01/12/00	OH	Columbus	Rickenbacker Intl	0/0343	ILS Rwy 23L, Orig–A...
01/12/00	OH	Waverly	Pike County	0/0335	GPS Rwy 25, Orig...
01/12/00	OH	Waverly	Pike County	0/0336	GPS Rwy 7, Orig...
01/12/00	OK	Guymon	Guymon Muni	0/0338	GPS Rwy 36, Orig...
01/12/00	TX	Brownsville	Brownsville/South Parde Island Intl.	0/0319	NDB or GPS Rwy 13R, Amdt 13...
01/13/00	AL	Tuscaloosa	Tuscaloosa Muni	0/0363	GPS Rwy 22 Orig...
01/13/00	AL	Tuscaloosa	Tuscaloosa Muni	0/0364	GPS Rwy 4 Orig–A...
01/13/00	OK	Guymon	Guymon Muni	0/0355	NDB Rwy 18, Amdt 5...
01/14/00	AK	Deadhorse	Deadhorse	0/0387	VOR/DME or Tacan Rwy 22, Amdt 2...
01/14/00	AK	Deadhorse	Deadhorse	0/0388	LOC/DME BC Rwy 22, Amdt 8...
01/14/00	AK	Sitka	Sitka Rocky Gutierrez	0/0375	LDA/DME Rwy 11, Amdt 13...
01/14/00	AK	Talkeetna	Talkeetna	0/0400	VOR/DME Rwy 36, Amdt 1A...
01/14/00	AK	Talkeetna	Talkeetna	0/0401	GPS Rwy 36, Orig...
01/14/00	AK	Talkeetna	Talkeetna	0/0404	NDB Rwy 36, Amdt 1A...
01/14/00	AK	Talkeetna	Talkeetna	0/0405	VOR–A Amdt 9A...
01/14/00	IN	South Bend	Michiana Regional Transportation Center.	0/0402	ILS Rwy 27L, Amdt 34A...
01/14/00	IN	South Bend	Michiana Regional Transportation Center.	0/0403	ILS Rwy 9R, Amdt 8A...
01/14/00	IN	South Bend	Michiana Regional Transportation Center.	0/0406	NDB or GPS Rwy 27L, Amdt 28A...
01/14/00	PA	Philadelphia	Northeast Philadelphia	0/0376	VOR or GPS Rwy 24, Amdt 18...
01/18/00	MN	Fairmont	Fairmont Muni	0/0444	VOR/DME Rwy 31, Amdt 1A...
01/18/00	MN	Fairmont	Fairmont Muni	0/0445	VOR/DME Rwy 31, Amdt 1A...
01/18/00	OH	Lima	Lima Allen County	0/0441	NDB or GPS Rwy 9, Amdt 2...
01/18/00	OH	Lima	Lima Allen County	0/0442	VOR or GPS Rwy 27, Amdt 14...
01/18/00	OH	Lima	Lima Allen County	0/0443	ILS Rwy 27, Amdt 2A...
01/18/00	TX	Brenham	Brenham Muni	0/0436	VOR/DME Rwy 16, Amdt 1A...
01/18/00	TX	Brenham	Brenham Muni	0/0438	GPS Rwy 34, Orig...
01/18/00	TX	Brenham	Brenham Muni	0/0439	NDB Rwy 16, Amdt 5A...
01/18/00	TX	Brownwood	Brownwood Regional	0/0447	LOC Rwy 17, Amdt 4...
01/18/00	TX	Brownwood	Brownwood Regional	0/0448	VOR or GPS Rwy 17, Amdt 11...
01/18/00	TX	Brownwood	Brownwood Regional	0/0449	VOR/DME or GPS Rwy 35, Amdt 1A...
01/18/00	WI	Appleton	Outagamie County Regional	0/0459	VOR/DME or GPS Rwy 21, Orig–A...

[FR Doc. 00–2249 Filed 2–1–00; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 29906; Amdt. No. 1970]

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: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125) telephone: (405) 954–4164.

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 (NFDC) 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 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.

Conclusion

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 January 21, 2000.

L. Nicholas Lacey,

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 February 24, 2000

Rifle, CO, Garfield County Regional, LOC/DME–A, Amdt 6

Rifle, CO, Garfield County Regional, ILS RWY 26, Orig

Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 9, Orig

Lawrenceville, IL, Lawrenceville-Vincennes Intl, VOR RWY 18, Amdt 1

Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAY RWY 18, Orig

Lawrenceville, IL, Lawrenceville-Vincennes Intl, VOR RWY 27, Amdt 7

Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 27, Orig

Lawrenceville, IL, Lawrenceville-Vincennes Intl, VOR RWY 36, Amdt 1

Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 36, Orig

Marshall, MO, Marshall Meml Muni, NDB RWY 36, Amdt 1

Marshall, MO, Marshall Meml Muni, RNAV RWY 18, Orig

Marshall, MO, Marshall Meml Muni, RNAV RWY 36, Orig

Lebanon, OH, Lebanon-Warren County, NDB–A, Amdt 5

Lebanon, OH, Lebanon-Warren County, RNAV RWY 1, Orig

Lebanon, OH, Lebanon-Warren County, RNAV RWY 19, Orig

Lubbock, TX, Lubbock Intl, NDB RWY 8, Amdt 1, CANCELLED

Martinsville, VA, Blue Ridge, LOC RWY 30, Orig

Martinsville, VA, Blue Ridge, SDF RWY 30, Amdt 2A, CANCELLED

Effective March 23, 2000

Minneapolis, MN, Minneapolis-St. Paul Intl (Wold-Chamberlain), NDB OR GPS RWY 4, Amdt 20

Minneapolis, MN, Minneapolis-St. Paul Intl (Wold-Chamberlain), ILS RWY 4, Amdt 27
Minneapolis, MN, Minneapolis-St. Paul Intl (Wold-Chamberlain), COPTER ILS RWY 30R, Orig
Beaumont, TX Beaumont Muni, GPS RWY 13, Orig

Effective April 20, 2000

Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 5, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 14, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 23, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 32, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, VOR/DME RNAV RWY 5, Amdt 3B, CANCELLED
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, VOR/DME RNAV RWY 23, Amdt 3A, CANCELLED
Fulton, MS, Fulton-Itawamba County, VOR/DME OR GPS–A, Orig CANCELLED

The FAA published a notice in Docket No. 29863, Amdt No. 1964 to Part 97 of the Federal Aviation Regulations (Vol 64 FR No. 243 Page 71019 dated December 20, 1999) which is hereby amended as follows:

Marquette, MI, Sawyer Intl, GPS RWY 19, Orig is hereby rescinded.

[FR Doc. 00–2248 Filed 2–1–00; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 97N–0481]

Gastroenterology-Urology Devices: Reclassification of the Penile Rigidity Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the penile rigidity implant from class III to class II when intended to provide penile rigidity in men diagnosed as having erectile dysfunction. The special control is the FDA guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.'' This action is taken on FDA's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the FDA Modernization Act of 1997.

DATES: This regulation is effective March 3, 2000.

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (CDRH) (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 16, 1997 (62 FR 65770), FDA issued a proposed rule to reclassify the penile rigidity implant from class III to class II based on new information respecting such device. FDA identified the guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'' as the special control capable of providing reasonable assurance of safety and effectiveness for the device.

Interested persons were given until March 16, 1998, to comment on the proposed rule. FDA received no comments on the proposed rule.

II. FDA's Conclusions

Based on a review of a substantial number of published studies referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA identified the following risks to health presented by the device: (1) Infection; (2) erosion, migration, and extrusion; (3) mechanical malfunction; (4) patient dissatisfaction; (5) adverse tissue reaction; (6) prolonged or intractable pain; (7) urinary obstruction; (8) silicone particle migration; and (9) other infrequently reported complications.

In the preamble to the proposed rule, FDA also noted that there is reasonable knowledge of the benefits of the device. Specifically, placement of the penile rigidity implant in men with erectile dysfunction typically provides sufficient penile rigidity for sexual intercourse and satisfaction rates in excess of 90 percent have been reported among penile rigidity implant recipients.

Based on its review of the cited studies, FDA determined that the guidance document would address adequately the risks to health discussed above by: (1) Labeling that would provide information to physicians and patients for the proper implantation and care of the device; (2) biocompatibility testing that would control the risk of adverse tissue reaction; (3) mechanical testing that would help control the risks of erosion, migration, extrusion, mechanical malfunction, and prolonged or intractable pain; (4) clinical data requirements for 510(k)'s that would help determine whether the risks presented by the device are within the limits established by existing devices; and (5) sterilization procedures and labeling that would guard against the implantation of an unsterile device.

FDA has concluded that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device and that the FDA guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'' is an adequate special control.

III. Electronic Access to Guidance Document

In order to receive the guidance entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (177) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or