

part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, July 5, 2007.

■ 1. The authority citation for part 95 continues to read as follows:
Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS
 [Amendment 468 effective date July 05, 2007]

From	To	MEA
§ 95.6001 VICTOR ROUTES—U.S.		
§ 95.6044 VOR Federal Airway V44 is Amended to Read in Part		
Baltimore, MD VORTAC *1700—MOCA.	Paleo, MD FIX	*2200
§ 95.6082 VOR Federal Airway V82 is Amended to Read in Part		
Gopher, MN VORTAC *2700—MOCA.	Farmington, MN VORTAC	*3500
§ 95.6093 VOR Federal Airway V93 is Amended to Read in Part		
Patuxent, MD VORTAC *10000—MRA. **1700—MOCA.	*Graco, MD FIX	**2500
*Graco, MD FIX *10000—MRA. **1600—MOCA.	Paleo, MD FIX	**10000
Paleo, MD FIX *1700—MOCA.	Baltimore, MD VORTAC	*2200
§ 95.6161 VOR Federal Airway V161 is Amended to Read in Part		
Farmington, MN VORTAC *2700—MOCA.	Gopher, MN VORTAC	*3500
§ 95.6369 VOR Federal Airway V369 is Amended to Read in Part		
Navasota, TX VORTAC *1800—MOCA	Groesbeck, TX VOR/DME	*2300 MAA—17500
Groesbeck, TX VOR/DME	Maverick, TX VOR/DME	3600 MAA—17500
§ 95.6379 VOR FEDERAL AIRWAY V379 is Amended to Read in Part		
Nottingham, MD VORTAC	Jetta, MD FIX	1900 MAA—17500
Jetta, MD FIX *10000—MRA **1600—MOCA	*Graco, MD FIX	**3000
Graco, MD FIX	Smyrna, DE VORTAC	MAA—17500 1800 MAA—17500
§ 95.6422 VOR FEDERAL AIRWAY V422 is Amended to Read in Part		
Wolf Lake, IN VOR	Twerp, OH FIX	2700

[FR Doc. E7-11143 Filed 6-11-07; 8:45 am]
 BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration
14 CFR Part 97
 [Docket No. 30553 Amdt. No. 3221]
Standard Instrument Approach Procedures, Weather Takeoff Minimums; Miscellaneous Amendments
AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.
SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and/or Weather Takeoff Minimums 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: This rule is effective June 12, 2007. The compliance date for each SIAP and/or Weather Takeoff Minimums is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of June 12, 2007.

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;

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

*For Purchase—*Individual SIAP and Weather Takeoff Minimums 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 and Weather Takeoff Minimums 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 (AFS-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 Title 14 of the Code of

Federal Regulations, Part 97 (14 CFR part 97), establishes, amends, suspends, or revokes SIAPs and/or Weather Takeoff Minimums. The complete regulatory description of each SIAP and/or Weather Takeoff Minimums 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 14 CFR part 97.20. The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4, 8260-5 and 8260-15A. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs and/or Weather Takeoff Minimums, 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 and/or Weather Takeoff Minimums but refer to their 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 and/or Weather Takeoff Minimums contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR sections, with the types and effective dates of the SIAPs and/or Weather Takeoff Minimums. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP and/or Weather Takeoff Minimums as contained in the transmittal. Some SIAP and/or Weather Takeoff Minimums amendments may have been previously issued by the FAA in a 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, and/or Weather Takeoff Minimums amendments may require making them effective in less than 30 days. For the remaining SIAPs and/or Weather Takeoff Minimums, an effective date at least 30 days after publication is provided.

Further, the SIAPs and/or Weather Takeoff Minimums contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and/or Weather Takeoff Minimums, 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/or Weather Takeoff Minimums and safety in air commerce, I find that notice and public procedure before adopting these SIAPs and/or Weather Takeoff Minimums are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs and/or Weather Takeoff Minimums 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, Incorporation by reference, and Navigation (air).

Issued in Washington, DC, on June 1, 2007.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, under Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and Weather Takeoff Minimums effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721-44722.

■ 2. Part 97 is amended to read as follows:

Effective 05 July 2007

Adak Island, AK, Adak, Takeoff Minimums and Textual DP, Amdt 1
 Los Angeles, CA, Los Angeles Intl, ILS OR LOC RWY 7L, Amdt 6A
 Washington, DC, Washington Dulles Intl, CONVERGING ILS RWY 12, Amdt 5
 Daytona Beach, FL, Daytona Beach Intl, ILS OR LOC RWY 7L, Amdt 30
 Oxford, ME, Oxford County Regional, Takeoff Minimums and Obstacle DP, Amdt 1
 Bemidji, MN, Bemidji Regional, LOC/DME RWY 25, Orig
 Charleston, WV, Yeager, ILS OR LOC RWY 5, Amdt 5
 Charleston, WV, Yeager, ILS OR LOC RWY 23, Amdt 29
 Charleston, WV, Yeager, Takeoff Minimums and Textual DP, Amdt 6

Effective 02 Aug 2007

Guntersville, AL, Guntersville Muni—Joe Starnes Field, Takeoff Minimums and Obstacle DP, Amdt 1
 Milton, FL, Peter Prince Fld, RNAV (GPS) RWY 36, Orig
 Milton, FL, Peter Prince Fld, GPS RWY 36, Amdt 1, CANCELLED
 Panama City, FL, Panama City—Bay Co Intl, Takeoff Minimums and Obstacle DP, Amdt 1
 Bemidji, MN, Bemidji Regional, Takeoff Minimums and Textual DP, Amdt 3
 Mocksville, NC, Twin Lakes, Takeoff Minimums and Obstacle DP, Orig
 Williamston, NC, Martin County, Takeoff Minimums and Obstacle DP, Orig
 Barnwell, SC, Barnwell Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2
 Darlington, SC, Darlington County Jetport, RNAV (GPS) RWY 5, Orig
 Darlington, SC, Darlington County Jetport, GPS RWY 5, Orig, CANCELLED
 Lancaster, SC, Lancaster County—McWhirter Field, VOR/DME-A, Orig
 Portland, TN, Portland Muni, Takeoff Minimums and Textual DP, Orig

Effective 30 Aug 2007

Lake Providence, LA, Byerley, NDB RWY 17, Amdt 2, CANCELLED
 Weatherford, OK, Thomas P. Stafford, NDB RWY 17, Amdt 3, CANCELLED
 Middleton, WI, Middleton Muni—Mory Field, RNAV (GPS) RWY 28, Amdt 1
 Sheboygan, WI, Sheboygan County Memorial, RNAV (GPS) RWY 3, Amdt 1
 Sheboygan, WI, Sheboygan County Memorial, RNAV (GPS) RWY 21, Amdt 1

Note: The FAA published the following Amendment in Docket No. 30551 Amdt No. 3219 to Part 97 of the Federal Aviation Regulations (Vol. 72, FR No. 104, page 30256, dated, May 31, 2007) Under Section 97.15 effective July 5, 2007, which is hereby corrected to be effective for August 30, 2007.

Newport News, VA, Williamsburg Intl, Takeoff Minimums and Obstacle DP, Orig

[FR Doc. E7-11147 Filed 6-11-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 888**

[Docket No. 2006N-0019]

Orthopedic Devices; Reclassification of the Intervertebral Body Fusion Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenetic protein) in class III. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device. This reclassification is based upon on the recommendation of the Orthopaedic and Rehabilitation Devices Panel (the Panel).

EFFECTIVE DATE: July 12, 2007.

FOR FURTHER INFORMATION CONTACT: Jodi N. Anderson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850, 240-276-3680.

SUPPLEMENTARY INFORMATION:**I. Background**

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), and the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of

enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has done the following: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act (21 U.S.C. 360c(e)) governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon "new information." FDA can initiate a reclassification under section 513(e) of the act or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).)