

Rules and Regulations

Federal Register

Vol. 73, No. 27

Friday, February 8, 2008

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FARM CREDIT ADMINISTRATION

12 CFR Part 630

RIN 3052-AC40

Disclosure to Investors in System-Wide and Consolidated Bank Debt Obligations of the Farm Credit System; Effective Date

AGENCY: Farm Credit Administration.

ACTION: Notice of effective date.

SUMMARY: The Farm Credit Administration (FCA or Agency), through the FCA Board (Board), issued a direct final rule with opportunity for comment under part 630 on November 15, 2007 (72 FR 64129) amending our regulation on the external auditor's assessment of internal control over financial reporting concerning the System-wide annual report to investors. The opportunity for comment expired on December 17, 2007. The FCA received no comments and therefore, the direct final rule becomes effective without change. In accordance with 12 U.S.C. 2252, the effective date of the final rule is 30 days from the date of publication in the **Federal Register** during which either or both Houses of Congress are in session. Based on the records of the sessions of Congress, the effective date of the regulations is January 31, 2008.

DATES: *Effective Date:* The regulation amending 12 CFR part 630 published on November 15, 2007 (72 FR 64129) is effective January 31, 2008.

FOR FURTHER INFORMATION CONTACT:

Wade Wynn, Policy Analyst, Office of Regulatory Policy, Farm Credit Administration, McLean, Virginia 22102-5090, (703) 883-4414, TTY (703) 883-4434

or

Laura McFarland, Senior Attorney, Office of General Counsel, Farm Credit Administration, McLean,

Virginia 22102-5090, (703) 883-4020, TTY (703) 883-4020.

Authority: (12 U.S.C. 2252(a)(9) and (10)).

Dated: January 31, 2008.

Roland E. Smith,

Secretary, Farm Credit Administration Board.

[FR Doc. E8-2381 Filed 2-7-08; 8:45 am]

BILLING CODE 6705-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30591; Amdt. No. 3254]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This Rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures 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, adding new obstacles, or changing 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 February 8, 2008. The compliance date for each SIAP, associated Takeoff Minimums, and ODP 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 February 8, 2008.

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.

Availability—All SIAPs and Takeoff Minimums and ODPs are available online free of charge. Visit nfdc.FAA.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP 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.

FOR FURTHER INFORMATION CONTACT:

Harry. J. Hodges, 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 rule amends Title 14 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or revoking SIAPs, Takeoff Minimums and/or ODPs. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on 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 FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPs, in addition to their complex nature and the need for a special format make publication in the **Federal Register** expensive and impractical. Furthermore, airmen do not

use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead 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, Takeoff Minimums and ODP listed on FAA forms is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs and the effective dates of the SIAPs, the associated Takeoff Minimums, and ODPs. This amendment also identifies the airport and its location, the procedure, and the amendment number.

The Rule

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

Further, the SIAPs and Takeoff Minimums and ODPs 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 Takeoff Minimums and ODPs, 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, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure before adopting these SIAPs, Takeoff Minimums and ODPs 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, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on January 25, 2008.

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/or Takeoff Minimums and/or Obstacle Departure Procedures 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 13 MAR 2008

Ontario, CA, Ontario Intl, ILS OR LOC RWY 8L, Amdt 8A
Fairmont, MN, Fairmont Muni, ILS OR LOC RWY 31, Orig-C
Las Cruces, NM, Las Cruces Intl, ILS OR LOC RWY 30, Amdt 2A
Hobart, OK, Hobart Muni, RNAV (GPS) RWY 17, Amdt 1
Hobart, OK, Hobart Muni, RNAV (GPS) RWY 35, Amdt 1
Hobart, OK, Hobart Muni, VOR RWY 35, Amdt 9
Hobart, OK, Hobart Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Blacksburg, VA, Virginia Tech/Montgomery Executive, Takeoff Minimums and Obstacle DP, Amdt 4
Roanoke, VA, Roanoke Regional/Woodrum Field, VOR/DME–A, Amdt 6
Seattle, WA, Boeing Field/King County Intl, RNAV (RNP) Z RWY 13R, Orig-A

Effective 10 APR 2008

Dothan, AL, Dothan Regional, ILS OR LOC RWY 32, Amdt 8
Dothan, AL, Dothan Regional, RNAV (GPS) RWY 14, Amdt 1

Dothan, AL, Dothan Regional, RNAV (GPS) RWY 32, Orig
Dothan, AL, Dothan Regional, VOR OR TACAN–A, Amdt 12
Dothan, AL, Dothan Regional, Takeoff Minimums and Obstacle DP, Orig
Evergreen, AL, Middleton Field, RNAV (GPS) RWY 1, Orig
Evergreen, AL, Middleton Field, RNAV (GPS) RWY 10, Orig
Evergreen, AL, Middleton Field, RNAV (GPS) RWY 19, Orig
Evergreen, AL, Middleton Field, RNAV (GPS) RWY 28, Orig
Evergreen, AL, Middleton Field, VOR/DME RWY 10, Amdt 3
Evergreen, AL, Middleton Field, Takeoff Minimums and Obstacle DP, Amdt 1
Anaktuvuk Pass, AK, Anaktuvuk Pass, RNAV (GPS)–A, Orig
Anaktuvuk Pass, AK, Anaktuvuk Pass, NDB–B, Amdt 1
Anaktuvuk Pass, AK, Anaktuvuk Pass, GPS–A, Orig, CANCELLED
Anaktuvuk Pass, AK, Anaktuvuk Pass, Takeoff Minimums and Obstacle DP, Amdt 1
Galena, AK, Edward G. Pitka, Sr. ILS OR LOC/DME RWY 25, Amdt 1A
St Mary's, AK, St. Marys, RNAV (GPS) Y RWY 17, Amdt 2
St Mary's, AK, St. Marys, RNAV (GPS) Y RWY 35, Amdt 1
St Mary's, AK, St. Marys, RNAV (GPS) Z RWY 17, Orig
St Mary's, AK, St. Marys, RNAV (GPS) Z RWY 35, Orig
St Mary's, AK, St. Marys, LOC/DME RWY 17, Amdt 4
St Mary's, AK, St. Marys, NDB RWY 35, Amdt 1
Oroville, CA, Oroville Muni, NDB RWY 1, Amdt 3, CANCELLED
Petaluma, CA, Petaluma Muni, VOR RWY 29, Orig, CANCELLED
Red Bluff, CA, Red Bluff Muni, NDB RWY 33, Amdt 2A, CANCELLED
Middletown, DE, Summit, VOR OR GPS–B Amdt 1B, CANCELLED
Preston, MN, Fillmore County, RNAV (GPS) RWY 29, Orig.
Preston, MN, Fillmore County, (GPS) RWY 29, Orig, CANCELLED
Newport, OR, Newport Muni, ILS OR LOC RWY 16, Amdt 1B
North Bend, OR, Southwest Oregon Regional, ILS OR LOC RWY 4, Amdt 6B
Myrtle Beach, SC, Myrtle Beach Intl, RADAR 1, Amdt 1C, CANCELLED
Rock Hill, SC, Rock Hill/York Co/Bryant Field, ILS OR LOC RWY 2, Amdt 1
Rock Hill, SC, Rock Hill/York Co/Bryant Field, RNAV (GPS) RWY 2, Orig
Rock Hill, SC, Rock Hill/York Co/Bryant Field, RNAV (GPS) RWY 20, Orig
Rock Hill, SC, Rock Hill/York Co/Bryant Field, GPS RWY 2, Orig-C, CANCELLED
Rock Hill, SC, Rock Hill/York Co/Bryant Field, GPS RWY 20, Orig-C, CANCELLED
Rock Hill, SC, Rock Hill/York Co/Bryant Field, VOR OR GPS–A, Amdt 9C, CANCELLED
Ogden, UT, Ogden-Hinckley, Takeoff Minimums and Obstacle DP, Amdt 2
Newport, VT, Newport State, NDB–A, Amdt 3, CANCELLED

Riverton, WY, Riverton Regional, ILS OR LOC RWY 28, Amdt 1B
Martinsburg, WV, Eastern WV Regional/Shepherd, LOC/DME BC RWY 8, Amdt 6, CANCELLED

The FAA published an Amendment in Docket No. 30587, Amdt No. 3251 to Part 97 of the Federal Aviation Regulations (Vol. 73, FR No. 16, Page 4073 dated Thursday, January 24, 2008) under section 97.29 effective March 13, 2008, which is hereby corrected to read as follows:

Waterville, ME, ILS OR LOC RWY 5, Amdt 2B

The FAA published an Amendment in Docket No. 30587, Amdt No. 3251 to Part 97 of the Federal Aviation Regulations (Vol. 73, FR No. 16, Page 4073 dated Thursday, January 24, 2008) under section 97.29 effective April 10, 2008, which is hereby rescinded:

Burlington, VT, Burlington Intl, ILS OR LOC/DME RWY 33, Amdt 1

The FAA published an Amendment in Docket No. 30587, Amdt No. 3251 to Part 97 of the Federal Aviation Regulations (Vol. 73, FR No. 16, Page 4073 dated Thursday, January 24, 2008) under section 97.29 effective February 14, 2008, which is hereby corrected to read as follows:

Omaha, NE, Epply Airfield, ILS OR LOC RWY 32L, Amdt 1

Omaha, NE, Epply Airfield, ILS OR LOC/DME RWY 14L, Amdt 1

Omaha, NE, Epply Airfield, ILS OR LOC/DME RWY 14R, ILS RWY 14R (CAT II), ILS RWY 14R (CAT III), Amdt 4

Omaha, NE, Epply Airfield, RNAV (GPS) RWY 14L, Amdt 1

Omaha, NE, Epply Airfield, Takeoff Minimums and Obstacle DP, Amdt 5

[FR Doc. 08-535 Filed 2-7-08; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 607, 610, and 640

[Docket No. FDA-2008-N-0067]

Revisions to the Requirements Applicable to Blood, Blood Components and Source Plasma; Confirmation of Effective Date and Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date and technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of February 19, 2008, for the direct final rule that appeared in the *Federal Register* of August 16, 2007 (72 FR 45883). The direct final rule amends the biologics regulations by removing,

revising, or updating specific regulations applicable to blood, blood components and Source Plasma to be more consistent with current practices in the blood industry and to remove unnecessary or outdated requirements. In addition, FDA is making technical amendments to the biologics regulations in response to comments received on the direct final rule.

DATES: The effective date for the regulation is confirmed as February 19, 2008. The effective date of the technical amendment is also February 19, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 16, 2007 (72 FR 45883), FDA solicited comments concerning the direct final rule for a 75-day period ending October 30, 2007. FDA stated that the effective date of the direct final rule would be on February 19, 2008, 6 months after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA received several letters of comment on the direct final rule; however, FDA did not receive any significant adverse comments. Therefore, FDA is confirming the effective date of the direct final rule and making two technical amendments in response to comments received. Comments were received from private industry, an individual, organizations representing the blood industry, and an employee of the Food and Drug Administration. The comments received and FDA's responses to the comments are discussed below as follows:

Two comments stated that under paragraph (c) of 21 CFR 610.53, there was an error in a temperature listed in the table under Red Blood Cells Deglycerolized and Red Blood Cells Frozen.

FDA agrees. In the *Federal Register* of September 24, 2007 (72 FR 54208), FDA issued a notice to correct a typographical error in the codified section of the direct final rule. The table in paragraph (c) of section 610.53 was corrected by replacing 65°C with -65°C.

One comment requested clarification of the proposed change in wording from "toward" to "at" concerning the specified temperature range under 21 CFR 640.4(h) because coolers do not have the capacity to maintain a temperature range between 1 and 10°C.

FDA agrees with the comment and therefore, is revising the regulation to use "toward" rather than "at".

One comment requested that under 21 CFR 640.24(d) the pH be revised from "not less than 6.0" to "not less than 6.2" to be consistent with the change in 21 CFR 640.25(b)(2) (§ 640.25(b)(2)) and with industry practice.

Because both of these provisions refer to the same pH requirement, FDA agrees and is revising 21 CFR 640.24(d) as requested.

One comment agreed with the change in pH under § 640.25(b)(2) but stated that there was no mention of the number of units that must meet this requirement and therefore the assumption is that 100 percent of the units must meet the requirement which they believe is unachievable.

We believe that the four units we require to be tested for quality control purposes under § 640.25(b) must meet the criteria listed under this regulation. However, FDA recently issued a document entitled "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods," dated December 2007 (December 17, 2007; 72 FR 71418). In this guidance, we provide recommendations on quality control monitoring. Therefore, no additional changes are warranted.

Two comments requested that FDA revise the definition under 21 CFR 640.30(a) to include "for intravenous or further manufacturing use" to facilitate use of plasma for further manufacturing use that has been collected concurrently with the collection of another blood component by apheresis. In addition, the comments requested that 21 CFR 640.34 and other provisions in the regulations be revised and harmonized to allow interchangeability of the plasma from intravenous use to manufacturing use after blood collection.

FDA presently has this issue under consideration and may address this in future rulemaking, if warranted. This comment is beyond the scope of this rulemaking.

One comment requested that FDA provide the rationale for the revision to 21 CFR 640.34(b) requiring fresh frozen plasma collected by an apheresis procedure to be prepared from blood collected by single uninterrupted venipuncture, and why it was differentiated from other components collected by apheresis. The comment also questioned whether the current practice of using a sterile connecting device to attach a sterile needle in the event of blood flow interruption would be prohibited in the future.