DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18010; Airspace Docket No. 04–ACE–39]

Modification of Class E Airspace; Broken Bow, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of the direct final rule which revises Class E airspace at Broken Bow, NE.

EFFECTIVE DATE: 0901 UTC, September 30, 2004.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on June 18, 2004 (69 FR 34060). The **Federal Register** subsequently published a correction to the direct final rule on June 28, 2004 in the Corrections Section (69 FR 36164–37162). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on September 30, 2004. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO, on July 29, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–18061 Filed 8–6–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30420; Amdt. No. 3102]

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: This rule is effective August 9, 2004. The compliance date for each SIAP 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 August 9, 2004.

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 Flight Inspection Area Office which originated the SIAP; 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 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, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC on July 30, 2004.

James J. Ballough,

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 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 September 30, 2004

Prescott, AZ, Ernest A. Love Field, RNAV (GPS) Rwy 21L, Amdt 1
Corning, AR, Corning Muni, RNAV (GPS) Rwy 18, Orig
Corning, AR, Corning Muni, RNAV (GPS) Rwy 36, Orig
Corning, AR, Corning Muni, GPS Rwy 18, Orig–A, Cancelled
Corning, AR, Corning Muni, GPS Rwy 36, Orig–A, Cancelled
Corning, AR, Corning Muni, VOR/DME–A, Amdt 2
Magnolia, AR, Magnolia Muni, RNAV (GPS) Rwy 18, Orig
Magnolia, AR, Magnolia Muni, RNAV (GPS) Rwy 36, Orig
Magnolia, AR, Magnolia Muni, GPS Rwy 18, Amdt 1, Cancelled
Magnolia, AR, Magnolia Muni, GPS Rwy 36, Amdt 1, Cancelled
Rogers, AR, Rogers Municipal-Carter Field, RNAV (GPS) Rwy 1, Orig
Rogers, AR, Rogers Municipal-Carter Field, GPS Rwy 1, Orig–A, Cancelled
Rogers, AR, Rogers Municipal-Carter Field, NDB Rwy 19, Amdt 1
Rogers, AR, Rogers Municipal-Carter Field, ILS or LOC Rwy 19, Amdt 3
Rogers, AR, Rogers Municipal-Carter Field, RNAV (GPS) Rwy 19, Orig
Alturas, CA, Alturas Muni, RNAV (GPS) Rwy 31, Orig
Alturas, CA, Alturas Muni, GPS Rwy 31, Orig–A, Cancelled
Oakland, CA, Metropolitan Oakland Intl, VOR Rwy 9R, Amdt 8
Oakland, CA, Metropolitan Oakland Intl, VOR/DME Rwy 27L, Amdt 11B
San Luis Obispo, CA, San Luis County Regional, VOR or TACAN–A, Amdt 6B
Vacaville, CA, Nut Tree, RNAV (GPS) Rwy 20, Orig
Vacaville, CA, Nut Tree, VOR–A, Amdt 4B
Vacaville, CA, Nut Tree, GPS Rwy 20, Amdt 1B, Cancelled
Tallahassee, FL, Tallahassee Regional, RADAR–1, Amdt 5
Tallahassee, FL, Tallahassee Regional, NDB Rwy 36, Amdt 20
Tallahassee, FL, Tallahassee Regional, VOR Rwy 18, Amdt 11
Tallahassee, FL, Tallahassee Regional, ILS or LOC/DME Rwy 36, Amdt 24
Tallahassee, FL, Tallahassee Regional, ILS or LOC Rwy 27, Amdt 8; ILS Rwy 27 (CAT II), Amdt 8
Tallahassee, FL, Tallahassee Regional, RNAV (GPS) Rwy 36, Orig
Tallahassee, FL, Tallahassee Regional, RNAV (GPS) Rwy 18, Orig
Tallahassee, FL, Tallahassee Regional, RNAV (GPS) Rwy 9, Amdt 1
Tallahassee, FL, Tallahassee Regional, RNAV (GPS) Rwy 27, Amdt 1
Arco, ID, Arco-Butte County, RNAV (GPS)–A, Orig
Sandpoint, ID, Sandpoint, LOC/DME–A, Amdt 1
Marion, IN, Marion Muni, RNAV (GPS) Rwy 4, Orig
New Orleans, LA, Louis Armstrong New Orleans Intl, RNAV (GPS) Y Rwy 19, Orig–A
New Orleans, LA, Louis Armstrong New Orleans Intl, RNAV (GPS) Z Rwy 19, Orig–A
New Orleans, LA, Louis Armstrong New Orleans Intl, ILS or LOC Rwy 28, Amdt 6
New Orleans, LA, Louis Armstrong New Orleans Intl, RNAV (GPS) Rwy 28, Orig–A
Tupelo, MS, Tupelo Regional, ILS or LOC Rwy 36, Amdt 7D
St. Louis, MO, Lambert-St. Louis Intl, ILS or LOC Rwy 6, Amdt 1
St. Louis, MO, Lambert-St. Louis Intl, ILS or LOC Rwy 24, Amdt 46
Polson, MT, Polson, RNAV (GPS) Rwy 18, Orig
Polson, MT, Polson, RNAV (GPS) Rwy 36, Orig
Stevensville, MT, Stevensville, GPS–A, Orig–A, Cancelled
Stevensville, MT, Stevensville, RNAV (GPS)–A, Orig
Lexington, NE, Jim Kelly Field, VOR Rwy 14, Amdt 4
Lexington, NE, Jim Kelly Field, NDB Rwy 14, Amdt 3
Lexington, NE, Jim Kelly Field, RNAV (GPS) Rwy 14, Orig
Lexington, NE, Jim Kelly Field, RNAV (GPS) Rwy 32, Orig
Lexington, NE, Jim Kelly Field, GPS Rwy 32, Orig–A, Cancelled
Belen, NM, Alexander Muni, RNAV (GPS) Rwy 21, Orig
Belen, NM, Alexander Muni, GPS Rwy 21, Orig, Cancelled
Clovis, NM, Clovis Muni, RNAV (GPS) Rwy 4, Orig
Clovis, NM, Clovis Muni, RNAV (GPS) Rwy 22, Orig
Clovis, NM, Clovis Muni, RNAV (GPS) Rwy 30, Orig
Clovis, NM, Clovis Muni, GPS Rwy 4, Orig, Cancelled
Clovis, NM, Clovis Muni, GPS Rwy 22, Orig–A, Cancelled
Clovis, NM, Clovis Muni, GPS Rwy 30, Amdt 1, Cancelled
Tucumcari, NM, Tucumcari Muni, RNAV (GPS) Rwy 3, Orig
Tucumcari, NM, Tucumcari Muni, GPS Rwy 3, Orig–A, Cancelled
Tucumcari, NM, Tucumcari Muni, RNAV (GPS) Rwy 21, Orig
Tucumcari, NM, Tucumcari Muni, VOR Rwy 21, Amdt 6

Tucumcari, NM, Tucumcari Muni, RNAV (GPS) Rwy 26, Orig
Tucumcari, NM, Tucumcari Muni, VOR Rwy 26, Amdt 6
Punxsutawney, PA, Punxsutawney Muni, RNAV (GPS) Rwy 25, Orig
Punxsutawney, PA, Punxsutawney Muni, VOR/DME–A, Amdt 1
Isla De Vieques, PR, Antonio Rivera Rodriguez, RNAV (GPS) Rwy 9, Amdt 1A
Eastland, TX, Eastland Muni, RNAV (GPS) Rwy 35, Amdt 1
Palestine, TX, Palestine Muni, VOR/DME Rwy 18, Amdt 5
Palestine, TX, Palestine Muni, NDB Rwy 18, Amdt 4
Palestine, TX, Palestine Muni, RNAV (GPS) Rwy 18, Orig
Palestine, TX, Palestine Muni, NDB Rwy 36, Amdt 8
Palestine, TX, Palestine Muni, RNAV (GPS) Rwy 36, Amdt 1
Petersburg, VA, Dinwiddie County, VOR Rwy 23, Amdt 5
Petersburg, VA, Dinwiddie County, LOC Rwy 5, Amdt 1
Petersburg, VA, Dinwiddie County, NDB Rwy 5, Amdt 5
Petersburg, VA, Dinwiddie County, RNAV (GPS) Rwy 5, Orig
Petersburg, VA, Dinwiddie County, RNAV (GPS) Rwy 23, Orig

[FR Doc. 04–17927 Filed 8–6–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2002N–0500]

General and Plastic Surgery Devices; Classification of Silicone Sheeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars into class I (general controls). As a class I device, the device will be exempt from premarket notification requirements. This action is taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Devices User Fee Modernization Act of 2002 (MDUFMA).

DATES: This rule is effective September 8, 2004.

FOR FURTHER INFORMATION CONTACT: Sam R. Arepelli, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 2003 (68 FR 13639), FDA issued a proposed rule to classify silicone sheeting intended to manage hyperproliferative scars on intact skin into class I based on available information regarding this device, including the recommendation of the General and Plastic Surgery Devices Panel (the Panel). The device is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars. FDA invited interested persons to comment on the proposed rule by June 18, 2003.

II. Summary of the Comments and FDA's Response

FDA received two comments on the proposed rule. One comment supported the proposed classification. The other comment expressed concerns about the proposal to classify the device into class I and exempt it from premarket notification. The comment recommended that FDA require premarket notification for silicone sheeting as recommended by the Panel. Specifically:

1. The comment stated that the proposed classification conflicts with the July 8, 2002, Panel recommendation of classification into class I subject to general controls, including premarket notification.

We agree that the Panel's recommendation was that this device be classified into class I subject to general controls, including premarket notification. Under the act, however, class I devices are presumptively exempt from premarket notification unless the class I device is ''intended for a use which is of substantial importance in preventing impairment of human health,'' or ''presents a potential unreasonable risk of illness or injury'' (section 510(l) of the act (21 U.S.C. 360(l))). In response to the specific question of whether this device is ''for a use which is of substantial importance in preventing impairment of human health,'' the Panel responded no. In response to the question of whether the device ''present[s] a potential unreasonable risk of illness or injury,'' the Panel again responded no. Thus, although the Panel's recommendation was that FDA require premarket notification, when asked whether the device presented the specific characteristics that would prevent exempting the device from premarket notification under section 510(l) of the act, the Panel's response was no.

As discussed in the proposed rule (68 FR 13639), FDA's experience with similar device types, specifically four other types of wound dressings, has demonstrated that classification as class I and exemption from premarket notification provide a reasonable assurance of safety and effectiveness. FDA believes that its experience with these devices is directly relevant to this determination and supports the exemption of this device from premarket notification. As discussed later in this document, FDA also believes this device presents a low risk to health and that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

Finally, FDA is not required to follow the Panel's recommendations, (section 513(b)(7) of the act (21 U.S.C. 360c(b)(7))) and for the reasons outlined in this preamble, FDA has determined that exempting this device from premarket notification requirements is appropriate.

2. The comment also stated that there is insufficient valid scientific evidence from prospective randomized clinical trials that: (1) Shows that the device is effective in either alleviating the symptoms or improving the appearance of hypertrophic or keloid scars, and (2) explains the device's mechanism of action. The comment further stated that keloid scars are more common among African-Americans and Asian-Americans and that no studies have investigated the effectiveness of silicone sheeting on a representative number of individuals across racial, sexual, or age categories.

FDA agrees in part. FDA reviewed the cited literature relating to this comment, as well as all other publicly available information on the device type. FDA acknowledges that the literature on this preamendments device does not demonstrate that silicone sheeting alone alleviates the symptoms or improves the appearance of hypertrophic or keloid scars, and that the literature does not focus on the performance of the device in specific ethnic or racial groups.

Consistent with the Panel's recommendation, however, FDA believes that class I is the appropriate classification for silicone sheeting