Actions	Compliance	Procedures
(3) Remove the red mark on the airspeed indicator (formerly required by AD 2001–26–25) at 165 kilometers/hour (km/h), 89.1 knots (kts), or 102.5 miles per hour (mph).	Before further flight after installing the additional mass balance and determining the empty weight and empty weight center of gravity required by paragraph (e)(1) of this AD.	Follow GROB Luft-und Raumfahrt Service Bulletin No. MSB306–36/3, dated December 4, 2002, and GROG Luft-und Raumfahrt Service Installation Instruction No. MSB306–36/3, dated April 18, 2002. The applicable sailplane maintenance manual also addresses this issue.
(4) Remove the red placard to the airspeed indicator (formerly required by AD 2001–26–25) restricting the Vne airspeed to 165 km/h, 89.1 kts, or 102.5 mph (according to the airspeed indicator calibration).	Before further flight after installing the additional mass balance and determining the empty weight and empty weight center of gravity required by paragraph (e)(1) of this AD.	Not applicable.

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, Small Airplane Directorate, FAA. For information on any already approved alternative methods of compliance, contact Greg Davison, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4130; facsimile: (816) 329–4090.

Does This AD Incorporate Any Material by Reference?

(g) You must do the actions required by this AD following the instructions in GROB Luft-und Raumfahrt Service Bulletin No. MSB306–36/3, dated December 4, 2002; GROB Luft-und Raumfahrt Service Installation Instructions No. MSB306–36/3, dated April 18, 2002; and Instructions for Continued Airworthiness GROB G 102, Revision 1, dated April 18, 2002. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may get a copy from GROB Luft-und Raumfahrt, Lettenbachstrasse 9, D–86874 Tussenhausen-Mattsies, Federal Republic of Germany; telephone: 49 8268 998139; facsimile: 49 8268 998200. You may review copies at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or at 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.*

Is There Other Information That Relates to This Subject?

(h) German AD Numbers 2001–317/4, dated January 9, 2003, and 2001–317/3, dated November 14, 2002, also address the subject of this AD.

Issued in Kansas City, Missouri, on August 13, 2004.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–18997 Filed 8–20–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30421; Amdt. No. 3103]

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 23, 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 23, 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 August 13, 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*

Huntsville, AL, Huntsville Intl-Carl T. Jones Field, VOR-A, Amdt 12
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, NDB RWY 18R, Amdt 13A
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, ILS OR LOC RWY 36L, Amdt 9
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, ILS OR LOC RWY 36R, Amdt 1
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, RADAR–1, Amdt 9
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, RNAV (GPS) Z RWY 36L, Orig
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, RNAV (GPS) Z RWY 36R, Orig
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, RNAV (GPS) Y RWY 36R, Orig
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, RNAV (GPS) RWY 18R, Orig
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, RNAV (GPS) Y RWY 36L, Orig
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, ILS OR LOC RWY 18L, Amdt 3
Huntsville, AL, Huntsville Intl-Carl T. Jones Field, ILS OR LOC RWY 18R, Amdt 23, ILS RWY 18R (CAT II), ILS RWY 18R (CAT III), Amdt 23
Melbourne, FL, Melbourne Intl, RNAV (GPS) RWY 9L, Orig
Melbourne, FL, Melbourne Intl, RNAV (GPS) RWY 9R, Orig
Melbourne, FL, Melbourne Intl, RNAV (GPS) RWY 27L, Orig
Melbourne, FL, Melbourne Intl, RNAV (GPS) RWY 27R, Orig
Melbourne, FL, Melbourne Intl, VOR RWY 9R, Amdt 20
Melbourne, FL, Melbourne Intl, VOR RWY 27L, Amdt 12
Melbourne, FL, Melbourne Intl, NDB RWY 9R, Amdt 15
Melbourne, FL, Melbourne Intl, GPS RWY 9L, Orig-D, CANCELLED
Melbourne, FL, Melbourne Intl, GPS RWY 27R, Orig-B, CANCELLED
Greensboro, GA, Greene County Regional, RNAV (GPS) RWY 6, Orig
Greensboro, GA, Greene County Regional, RNAV (GPS) RWY 24, Orig
Greensboro, GA, Greene County Regional, VOR/DME-B, Amdt 1
Greensboro, GA, Greene County Regional, NDB RWY 24, Amdt 1
Greensboro, GA, Greene County Regional, LOC RWY 24, Amdt 2
Greensboro, GA, Greene County Regional, GPS RWY 24, Orig-A, CANCELLED
Greensboro, GA, Greene County Regional, GPS RWY 6, Orig-A, CANCELLED
St. Marys, GA, St Marys, RADAR–1, Amdt 2
Caribou, ME, Caribou Muni, VOR-A, Amdt 11
Caribou, ME, Caribou Muni, RNAV (GPS) RWY 19, Orig
Caribou, ME, Caribou Muni, GPS RWY 19, Orig, CANCELLED
Las Vegas, NV, McCarran Intl, ILS OR LOC RWY 25R, Amdt 16H
Rochester, NY, Greater Rochester Intl, VOR RWY 4, Amdt 10
Clayton, NM, Clayton Muni Arpk, NDB RWY 2, Amdt 1
Clayton, NM, Clayton Muni Arpk, NDB RWY 20, Amdt 1
Jackson, OH, James A. Rhodes, VOR/DME-A, Amdt 2
Jackson, OH, James A. Rhodes, RNAV (GPS) RWY 1, Amdt 1
Jackson, OH, James A. Rhodes, RNAV (GPS) RWY 19, Amdt 1
Urbana, OH, Grimes Field, VOR-A, Amdt 5C
Urbana, OH, Grimes Field, RNAV (GPS) RWY 2, Orig
Urbana, OH, Grimes Field, RNAV (GPS) RWY 20, Orig
Franklin, PA, Venango Regional, VOR RWY 3, Amdt 4
Franklin, PA, Venango Regional, VOR RWY 21, Amdt 7
Franklin, PA, Venango Regional, ILS OR LOC RWY 21, Amdt 5
Franklin, PA, Venango Regional, RNAV (GPS) RWY 3, Orig
Franklin, PA, Venango Regional, RNAV (GPS) RWY 21, Orig
Gainesville, TX, Gainesville Muni, RNAV (GPS) RWY 17, Orig-A
Leesburg, VA, Leesburg Executive, RNAV (GPS) RWY 17, Amdt 1

Stafford, VA, Stafford Regional, RNAV (GPS) RWY 33, Amdt 1

** * * Effective October 28, 2004*

Gwinner, ND, Gwinner-Roger Melroe Field, NDB RWY 34, Amdt 1
Gwinner, ND, Gwinner-Roger Melroe Field, RNAV (GPS) RWY 16, Orig
Gwinner, ND, Gwinner-Roger Melroe Field, RNAV (GPS) RWY 34, Orig

** * * Effective November 25, 2004*

Greencastle, IN, Putnam County, NDB RWY 18, Amdt 1

[FR Doc. 04–19160 Filed 8–20–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2003N–0390]

Dental Devices; Dental Noble Metal Alloys and Dental Base Metal Alloys; Designation of Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the identification and classification regulations of gold-based alloys and precious metal alloys for clinical use and base alloys devices in order to designate a special control for these devices. FDA is also exempting these devices from premarket notification requirements. The agency is taking this action on its own initiative. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance documents that would serve as special controls for these devices.

DATES: This rule is effective September 22, 2004.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext.123, e-mail: *mea@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Devices Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), 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 as follows: Class I (general controls), Class II (special controls), and Class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. Under the 1976 amendments, class II devices are identified as those devices in which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but for which there is sufficient information to establish a performance standard to provide such assurance.

The SMDA broadened the definition of class II devices to include those devices for which general controls would not provide reasonable assurance of the safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. The special controls include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary to provide such assurance. See section 513(a)(1)(B) of the act.

FDAMA added, among other sections, a new section 510(m) to the act (21 U.S.C. 360(m)). Under new section 510(m) of the act, FDA may exempt a class II device from premarket notification requirements (510(k)) (21 U.S.C. 360(k)), if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

In the **Federal Register** of December 1, 2003 (68 FR 67097), FDA issued a proposed rule to amend the classification regulation of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices. FDA identified the draft guidance documents entitled:''Class II Special Controls Guidance Document: Dental Precious Metal Alloys'' and ''Class II Special Controls Document: Dental Base Metal Alloys'' as the proposed special controls capable of providing reasonable assurance of the safety and effectiveness of these devices. FDA invited interested persons to comment on the proposed rule and the draft guidance documents by March 1, 2004. FDA received three comments.

II. Summary of Comments and FDA Response

FDA received one comment from a consumer and one (in duplicate) from a trade association. Both comments were in support of the proposed reclassification with minor modifications suggested. The subject of the consumer comment was that the name of the regulation ''gold based alloys and precious metal alloys for clinical use'' is unscientific since gold is, by definition, a precious metal.

FDA agrees that the name of the regulation is redundant and, accordingly, has changed the final rule to modify § 872.3060 to read ''noble metal,'' as the term encompasses all precious metals such as gold. The description ''for clinical use'' has been deleted because it is clear from the identification that such use is intended. For precision and clarity, we have also modified the identifications in §§ 872.3060 and 872.3710 to more precisely describe these alloys and their component metals.

The subject of the trade association comment was that: (1) The scope of the dental base metal alloys guidance is not clear as to what alloys are subject to the guidance and (2) the recommendation that the labeling for nickel-containing alloys contain a contraindication for hypersensitive individuals is unnecessary because nickel has been demonstrated to be biocompatible.

FDA agrees that more clarity is needed and has modified the scope of the guidance to define the devices not clearly addressed by the guidance. Regarding the second point, while FDA agrees that nickel has been demonstrated to be biocompatible for this intended use, FDA disagrees that the labeling should not contain a contraindication for nickel hypersensitive individuals. The agency believes this warning is needed to minimize the potential for adverse events associated with improper use of this device. Nickel, although biocompatible, is a known sensitizing agent for a small percentage of the population. FDA believes that removing this warning will increase the risk of the device by potentially exposing nickel-hypersensitive individuals who, otherwise, would not be exposed because of the current warning labels.