

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

* * * *Effective December 25, 2003*

North Little Rock, AR, North Little Rock Muni, RNAV (GPS) RWY 5, Orig.
 North Little Rock, AR, North Little Rock Muni, GPS RWY 5, Amdt. 1, Cancelled
 Searcy, AR, Searcy Muni, LOC RWY 1, Orig.
 Daytona Beach, FL, Daytona Beach Intl, LOC BC RWY 25R, Amdt. 15
 Daytona Beach, FL, Daytona Beach Intl, ILS RWY 7L, Amdt. 29
 Sandersville, GA, Kaolin Field, NDB OR GPS RWY 12, Amdt. 3, Cancelled
 Sandersville, GA, Kaolin Field, NDB RWY 12, Orig.
 St. Cloud, MN, St. Cloud Regional, ILS OR LOC RWY 31, Amdt. 3
 St. Cloud, MN, St. Cloud Regional, VOR/DME RWY 13, Orig.
 St. Cloud, MN, St. Cloud Regional, VOR RWY 31, Orig.
 St. Cloud, MN, St. Cloud Regional, NDB RWY 31, Amdt. 3
 St. Cloud, MN, St. Cloud Regional, VOR/DME RWY 13, Amdt. 8C, Cancelled
 St. Cloud, MN, St. Cloud Regional, VOR RWY 31, Amdt. 11, Cancelled
 Berlin, NH, Berlin Muni, RNAV (GPS) RWY 18, Orig.
 Berlin, NH, Berlin Muni, GPS RWY 18, Orig, Cancelled
 Berlin, NH, Berlin Muni, VOR-B, Amdt. 2A
 New York, NY, John F. Kennedy Intl, ILS RWY 22L, Amdt. 24
 Liberty, NC, Causey, RNAV (GPS) RWY 2, Orig.
 Liberty, NC, Causey, RNAV (GPS) RWY 20, Orig.
 Liberty, NC, Causey, VOR RWY 2, Amdt. 5
 Zanesville, OH, Zanesville Muni, ILS OR LOC/DME RWY 22, Orig.
 Ponca City, OK, Ponca City Rgnl, RNAV (GPS) RWY 17, Orig.
 Ponca City, OK, Ponca City Rgnl, GPS RWY 17, Orig., Cancelled
 Ponca City, OK, Ponca City Rgnl, RNAV (GPS) RWY 35, Orig.
 Ponca City, OK, Ponca City Rgnl, GPS RWY 35, Orig-A, Cancelled
 Wagoner, OK, Hefner-Easley, RNAV (GPS) RWY 18, Orig.
 Wagoner, OK, Hefner-Easley, RNAV (GPS) RWY 36, Orig.
 Newport News, VA, Newport News/Williamsburg Intl, NDB RWY 2, Amdt. 5
 Newport News, VA, Newport News/Williamsburg Intl, NDB RWY 20, Amdt. 4
 Newport News, VA, Newport News/Williamsburg Intl, RNAV (GPS) RWY 2, Orig.

Newport News, VA, Newport News/Williamsburg Intl, RNAV (GPS) RWY 20, Orig.

New Richmond, WI, New Richmond Muni, NDB RWY 14, Amdt. 2
 New Richmond, WI, New Richmond Muni, RNAV (GPS) RWY 14, Orig.
 New Richmond, WI, New Richmond Muni, RNAV (GPS) RWY 32, Orig.
 New Richmond, WI, New Richmond Muni, GPS RWY 32, Orig., Cancelled

* * * *Effective January 22, 2004*

Ada, OK, Ada Muni, VOR/DME-A, Orig.-D

* * * *Effective February 19, 2004*

Chevak, AK, Chevak, RNAV (GPS) RWY 14, Orig.

Chevak, AK, Chevak, RNAV (GPS) RWY 32, Orig.

Kivalina, AK, Kivalina, RNAV (GPS) RWY 12, Orig.

Kivalina, AK, Kivalina, RNAV (GPS) RWY 30, Orig.

Kotlik, AK, Kotlik, RNAV (GPS) RWY 02, Orig.

Kotlik, AK, Kotlik, RNAV (GPS) RWY 20, Orig.

Fort Worth, TX, Fort Worth Meacham Intl, NDB RWY 16, Amdt. 6

Fort Worth, TX, Fort Worth Meacham Intl, RNAV (GPS) RWY 16, Orig.

Quinton, VA, New Kent County, RNAV (GPS) RWY 10, Orig.

Quinton, VA, New Kent County, RNAV (GPS) RWY 28, Orig.

Quinton, VA, New Kent County, VOR-A, Amdt. 1

[FR Doc. 03-29844 Filed 12-1-03; 8:45 am]

BILLING CODE 4910-13-P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1260

RIN 2700-AC75

NASA Grant and Cooperative Agreement Handbook—Public Acknowledgements

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: This final rule amends the NASA Grant and Cooperative Agreement Handbook to include public acknowledgement of NASA's photographs and illustrations in reports or publications generated by NASA's award of grants or cooperative agreements.

EFFECTIVE DATE: December 2, 2003.

FOR FURTHER INFORMATION CONTACT: Paul Brundage, Code HK, (202) 358-0481, e-mail: paul.d.brundage@nasa.gov.

SUPPLEMENTARY INFORMATION:

A. Background

In publications generated from NASA's award of grants and cooperative agreements, principal investigators sometimes fail to acknowledge NASA's photographs and illustrations. This final rule sets forth NASA's desire for acknowledgement in 14 CFR 1260.22. NASA published a proposed rule in the **Federal Register** on August 15, 2003 (68 FR 48837). No comments were received. Therefore, the proposed rule is being adopted as final without change.

B. Regulatory Flexibility Act

NASA certifies that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because (a) few grants and cooperative agreements under 14 CFR part 1260 are awarded to small businesses, (b) it will only affect the few recipients of awards that make use of NASA photographs and illustrations in their publications, and (c) this final rule has no economic impact on award recipients since it only requests acknowledgment of the source of photographs and illustrations in the recipients' publications.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this rule does not impose any new recordkeeping or information collection requirements, or collection of information from offerors, contractors, or members of the public that require the approval of the Office of Management (OMB) and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 14 CFR Part 1260

Grant Programs—Science and Technology.

Tom Luedtke,

Assistant Administrator for Procurement.

■ Accordingly, 14 CFR Part 1260 is amended as follows:

■ 1. The authority citation for 14 CFR 1260 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1), Pub. L. 97-258, and 96 Stat. 1003 (31 U.S.C. 6301, *et seq.*).

PART 1260—GRANTS AND COOPERATIVE AGREEMENTS

■ 2. Amend the provision at section 1260.22 by revising the date and adding paragraph (a)(3) to read as follows:

§ 1260.22 Technical publications and reports.**Technical Publications and Reports
December 2003**

(a) * * *

(3) As a courtesy, any release of a NASA photograph or illustration should list NASA first on the credit line followed by the name of the Principal Investigator's Institution. An example follows:

"Photograph <or illustration, figure, etc.> courtesy of NASA <or NASA Center managing the mission or program> and the <Principal Investigator's institution>."

* * * * *

[End of provision]

[FR Doc. 03-29931 Filed 12-1-03; 8:45 am]

BILLING CODE 7510-01-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 872**

[Docket No. 2002N-0305]

**Medical Devices: Classification of the
Dental Sonography Device and Jaw
Tracking Device**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the dental sonography device into class I, when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is classifying the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. 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. FDA is taking this action 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 Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: This rule is effective January 2, 2004.

FOR FURTHER INFORMATION CONTACT:

Mary S. Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

SUPPLEMENTARY INFORMATION:**I. Background**

The act (21 U.S.C. 301 *et seq.*), as amended by 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 as a function of 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, FDA refers to 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: (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 FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) issues, under section 513(i) of the act, an order finding the device as substantially equivalent to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to preamendments devices by means of premarket notification

procedures as delineated in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments type device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Consistent with the act and the regulations, FDA consulted with the Dental Products Advisory Panel (the Panel), an FDA advisory committee, regarding the classification of the dental sonography device and the jaw tracking device.

II. Regulatory History of the Device

In the **Federal Register** of August 14, 2002 (67 FR 52901), FDA proposed to classify the dental sonography device into class I when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA also proposed to classify the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain.

FDA provided an opportunity for interested persons to comment on the proposed regulation and guidance document until November 12, 2002. FDA received one comment from a consumer, however, the comment was irrelevant to the proposed rule because it was referring to a different device. A manufacturer commented that the identification of the class II sonography could be read to place a device in class II even if it does not interpret sounds. The comment said that a device is appropriately in class II if it interprets sounds. The comment further suggested that FDA should define "interpret" to mean that the device provides a specific diagnosis and not just meaningful output.

FDA agrees that the identification may not have been clear and has revised § 872.2050(b) by combining the last two sentences to clarify that interpretation is a necessary part of the identification. FDA disagrees that "interpret" should mean that a device provides a specific diagnosis. FDA believes that it is necessary that the manufacturer of a class II dental sonography device that