

Amendment 39–13296 (68 FR 53496, September 11, 2003), with new service information. Except as provided by paragraph (j) of this AD: Prior to or concurrently with the accomplishment of the modification of the nacelle strut and wing structure required by paragraph (g) of this AD, accomplish the actions specified in Boeing Service Bulletin 757–54–0027, Revision 1, dated October 27, 1994; and Boeing Service Bulletin 757–54–0036, dated May 14, 1998, or Boeing Service Bulletin 757–54–0036, Revision 1, dated July 31, 2006; as applicable; in accordance with those service bulletins. As of the effective date of this AD, use only Boeing Service Bulletin 757–54–0027, Revision 1, dated October 27, 1994; and Boeing Service Bulletin 757–54–0036, Revision 1, dated July 31, 2006; to accomplish the applicable requirements of this paragraph.

**(i) Retained Repair With New Service Information**

This paragraph restates the requirements of paragraph (c) of AD 2003–18–05, Amendment 39–13296 (68 FR 53496, September 11, 2003), with new service information. If any damage to airplane structure is found during the accomplishment of the modification required by paragraph (g) of this AD, and Boeing Service Bulletin 757–54–0034, dated May 14, 1998; Boeing Service Bulletin 757–54–0034, Revision 1, dated October 11, 2001; or Boeing Service Bulletin 757–54–0034, Revision 2, dated May 7, 2009; specifies to contact Boeing for appropriate action: Before further flight, repair the damage using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

**(j) Retained Modification With New Service Information**

This paragraph restates the requirements of paragraph (d) of AD 2003–18–05, Amendment 39–13296 (68 FR 53496, September 11, 2003), with new service information. Modify the nacelle strut (including replacing the upper link with a new, improved part, and modifying the wire support bracket attached to the upper link), in accordance with Boeing Service Bulletin 757–54–0036, dated May 14, 1998; or Boeing Service Bulletin 757–54–0036, Revision 1, dated July 31, 2006; at the earlier of the times specified in paragraphs (j)(1) and (j)(2) of this AD. As of the effective date of this AD, use only Boeing Service Bulletin 757–54–0036, Revision 1, dated July 31, 2006, to accomplish the requirements of this paragraph.

(1) Prior to or concurrently with accomplishment of the modification of the nacelle strut and wing structure required by paragraph (g) of this AD.

(2) Prior to the accumulation of 27,000 total flight cycles (for Model 757–200 series airplanes) or 29,000 total flight cycles (for Model 757–200PF series airplanes), or within 2 years after October 16, 2003 (the effective date of AD 2003–18–05, Amendment 39–13296 (68 FR 53496, September 11, 2003)), whichever is later.

**(k) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Seattle Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: [9-ANM-Seattle-ACO-AMOC-Requests@faa.gov](mailto:9-ANM-Seattle-ACO-AMOC-Requests@faa.gov).

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs approved previously in accordance with AD 2003–18–05, Amendment 39–13296 (68 FR 53496, September 11, 2003), are approved as AMOCs for the corresponding provisions of this AD, except for AMOCs that approved a revised compliance time.

**(l) Related Information**

For more information about this AD, contact Nancy Marsh, Aerospace Engineer, Airframe Branch, ANM–120S, Seattle Aircraft Certification Office, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6440; fax: 425–917–6590; email: [Nancy.Marsh@faa.gov](mailto:Nancy.Marsh@faa.gov).

**(m) Material Incorporated by Reference**

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on June 20, 2013.

(i) Boeing Service Bulletin 757–54–0034, Revision 2, dated May 7, 2009.

(ii) Boeing Service Bulletin 757–54–0036, Revision 1, dated July 31, 2006.

(4) The following service information was approved for IBR on October 16, 2003 (68 FR 53496, September 11, 2003).

(i) Boeing Service Bulletin 757–54–0034, Revision 1, dated October 11, 2001.

(ii) Reserved.

(5) The following service information was approved for IBR on November 13, 2000 (65 FR 59703, October 6, 2000).

(i) Boeing Service Bulletin 757–54–0027, Revision 1, dated October 27, 1994.

(ii) Boeing Service Bulletin 757–54–0034, dated May 14, 1998.

(iii) Boeing Service Bulletin 757–54–0036, dated May 14, 1998.

(6) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; phone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: <https://www.myboeingfleet.com>.

(7) You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(8) You may view this service information that is incorporated by reference 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/cfr/ibr-locations.html>.

Issued in Renton, Washington, on May 6, 2013.

**Ali Bahrami,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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**DEPARTMENT OF ENERGY**

**Federal Energy Regulatory Commission**

**18 CFR Part 35**

[Docket No. RM12–3–000]

**Revisions to Electric Quarterly Report Filing Process; Availability of Draft XML Schema**

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Notification of availability.

**SUMMARY:** The Federal Energy Regulatory Commission is making available on its Web site (<http://www.ferc.gov>), Extensible Mark-Up Language (XML) needed to make Electric Quarterly Report (EQR) filings with one of the new filing processes adopted in Order No. 770, in the Commission's Final Rule, 77 FR 71288 (November 30, 2012). Please refer to the **SUPPLEMENTARY INFORMATION** Section below for details.

**DATES:** The XML is now available at the links mentioned below.

**FOR FURTHER INFORMATION CONTACT:** Christina Switzer, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First St. NE., Washington, DC 20426, (202) 502–6379.

**SUPPLEMENTARY INFORMATION:** Take notice that the Federal Energy Regulatory Commission (Commission) is making available on its Web site the

Extensible Mark-Up Language (XML) needed to make Electric Quarterly Report (EQR) filings with one of the new filing processes adopted in Order No. 770.<sup>1</sup> The Commission is also posting CSV file samples. Order No. 770 revised the process for filing EQRs. Pursuant to Order No. 770, one of the new processes for filing allows EQRs to be filed using an XML file. The XML schema that is needed to file EQRs in this manner is now posted on the Commission's Web site at <http://www.ferc.gov/docs-filing/eqr.asp>. While this schema remains subject to any necessary changes prior to the availability of the finalized schema, Commission staff anticipates that changes, if any, will be minor.

Any comments or questions concerning the XML schema may be directed to [eqr@ferc.gov](mailto:eqr@ferc.gov). Please include "XML Schema" in the subject line of any such email.

We encourage all EQR filers to subscribe to our *EQR RSS Feed* to stay up-to-date on all updates.

Dated: May 8, 2013.

**Kimberly D. Bose,**  
*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 880

[Docket No. FDA-2013-M-0042]

#### Medical Devices; General Hospital and Personal Use Monitoring Devices; Classification of the Ingestible Event Marker

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the ingestible event marker into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective June 17, 2013. The classification was applicable beginning July 10, 2012.

**FOR FURTHER INFORMATION CONTACT:** James Cheng, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1326, Silver Spring, MD 20993-0002, 301-796-6306.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144, July 9, 2012, 126 Statute 1054), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-

moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 7, 2012, classifying the Proteus Personal Monitor including ingestible event marker into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On May 14, 2012, Proteus Biomedical, Inc., submitted a petition requesting classification of the Proteus Personal Monitor including ingestible event marker under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and the medical literature, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name ingestible event marker, and it is identified as a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

FDA has identified the following risks to health associated with this type of

<sup>1</sup> Revisions to Electric Quarterly Report Filing Process, Order No. 770, 77 FR 71288 (Nov. 30, 2012), FERC Stats. & Regs. [Regulation Preambles] ¶ 31,338 (cross-referenced at 141 FERC ¶ 61,120) (Nov. 15, 2012).