Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 121 and 139

[Docket No. FAA–2000–7479; Notice No. 00–05]

RIN 2120–AG96

Certification of Airports; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; correction.

SUMMARY: This document contains corrections to the notice of proposed rulemaking (NPRM) published in the **Federal Register** on June 21, 2000 (65 FR 38636), which proposes to revise the current airport certification regulation and to establish certification requirements for airports serving scheduled air carrier operations in aircraft with 10–30 seats.

FOR FURTHER INFORMATION CONTACT: Linda Bruce, 202–267–8553; E-mail: linda.bruce@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

Comments on these corrections should be mailed or delivered, in duplicate, to: U.S. Department of Transportation Dockets, Docket No. FAA–2000–7479, 400 Seventh Street, S.W., Room Plaza 401, Washington, DC 20590. Comments also may be sent to or viewed electronically in the Dockets Management System (DMS) at the following Internet address: http://dms.dot.gov. Commenters who wish to file comments electronically should follow the instructions on the DMS web site.

Background

FAA issued an NPRM on June 21, 2000 (65 FR 38636), which proposes to revise the current airport certification regulation and to establish certification requirements for airports serving scheduled air carrier operations in aircraft with 10–30 seats. These proposed changes would require all operators of currently certficated airports to revise their airport certification manual or specifications and comply with new standards.

FAA requires under existing part 139 that airport operators comply with certain safety requirements prior to serving operations of large air carrier aircraft (aircraft designed for at least 31 passenger seats). When an airport operator satisfactorily complies with such requirements, FAA issues that airport operator an airport operating certificate that permits the airport operator to serve large air carrier aircraft.

FAA allows airport operators serving only unscheduled operations of large air carrier aircraft to comply with part 139 in a limited manner. These airport operators are issued a limited airport operating certificate, and under the proposal, would be reclassified as Class IV airports. There are approximately 15 airport operators that currently hold a limited airport operating certificate that would, under the proposal, be classified as Class IV airports.

As published, the NPRM contains errors regarding proposed requirements for Class IV airports that may be misleading to the public and are in need of correction. These errors are in a chart in the preamble (65 FR 38648) that compares current and proposed part 139 requirements, and in the chart contained in the proposed regulatory language of § 239.203(b)(65 FR 38673).

Both of these charts incorrectly indicate that Class IV airport operators would be required to include procedures in their airport certification manual for the handling and storage and hazardous materials, traffic and wind direction indicators, and self-inspections, but these procedures would not have to meet the requirements prescribed under subpart D. However, preamble language in the proposal (65 FR 38646, 65 FR 38655, 65 FR 38656, and 65 FR 38658) correctly states that all proposed airport classifications would be required to address these safety issues, in the manner required in subpart D.

These charts should have indicated that Class IV airport operators would need to address in their airport certification manual procedures for complying with subpart D requirements for the storage and handling of hazardous materials, wind and traffic indicators, and self-inspections. These new manual elements would be in addition to those already required, which include procedures for complying with personnel, paved and unpaved surfaces, safety areas, marking, lighting, signs, and airport conditions reporting requirements.

FAA believes the NPRM provided adequate notice of proposed requirements for Class IV airports, but is issuing this correction to the charts (65 FR 38648 and 65 FR 38673) out of an abundance of caution. FAA states in the proposal at 65 FR 38646 that most holders of a limited airport operating certificate already address in their airport certification specifications, in the manner required under proposed subpart D, procedures for the handling of hazardous materials, wind and traffic indicators, and self-inspections. No comments were received regarding this item as discussed at any of the three locations in the proposal.

Although the comment period for the NPRM has closed, the FAA does not believe that the public was confused about this proposal. Any comments received on these corrections will be considered to the extent practical prior to the issuance of the final rule.

In addition, there were other errors in the preamble chart found at 65 FR 38648. This chart should have indicated that the aircraft rescue and firefighting (ARFF) requirement would no longer be negotiated. Rather, Class IV airports would be required to comply with ARFF standards prescribed in proposed §§ 139.315, 139.317, and 139.319. The chart also should have stated that Class IV airport operators already comply with personnel provisions and airport condition reporting requirements of subpart D. In both instances, the proposed rule text regarding these requirements found at 65 FR 38674 (proposed § 139.203(b)) was correct.

Finally, there is a typographical error in the chart found in the rule text at 65 FR 38673. The reference to § 139.319(l) in § 139.203(b)(6) is incorrect. The reference should be to § 139.319(k).

Correction

In proposed rule FR Doc. 00–14524, published on June 21, 2000 (65 FR 38636), make the following corrections:

1. On page 38648, table D is corrected to read as follows:

D. CURRENT AND PROPOSED REQUIREMENTS FOR CLASS IV AIRPORTS

Current requirements	Proposed requirements
1. Personnel provisions	New requirement for a recordkeeping system and personnel training.
2. Paved and unpaved surfaces	Unchanged.
3. Safety areas	Unchanged.
4. Marking, lighting and signs	Unchanged.
5.	
6. ARFF (negotiated standard)	New ARFF standards (per proposed § 139.315–321).
7. HAZMAT handling/storage (negotiated standard)	New HAZMAT handling/storage standard (per proposed § 139.323).
8. Traffic/wind indicators (negotiated standard)	New traffic/wind indicators standard (per proposed § 139.325).
9.	New requirement for an AEP (no triennial exercise required).
10. Self-inspections (negotiated standard)	New self-inspection standard (per proposed § 139.329).
11.	
12.	
13.	
14.	
15.	
16. Airport condition reporting	New notification standard.
17.	

2. On page 38673, the table in § 139.203 is corrected to read as follows:

§ 139.203 Contents of airport certification manual.

* * * * *

REQUIRED AIRPORT CERTIFICATION MANUAL ELEMENTS

Manual elements	Airport certificate class			
	Class I	Class II	Class III	Class IV
1. Lines of succession of airport operational responsibility	X	X	X	X
2. Each current exemption issued to the airport from the requirements of this part	X	X	X	X
3. Any limitations imposed by the Administrator	X	X	X	X
4. A grid map or other means of identifying locations and terrain features on and around the airport which are significant to emergency operations	X	X	X	X
5. The location of each obstruction required to be lighted or marked within the airport's area of authority	X	X	X	X
6. A description of each movement area available for air carriers and its safety areas and each road described in § 139.319(k) that serves it	X	X	X	X
7. Procedures for avoidance of interruption or failure during construction work of utilities serving facilities or navaids that support air carrier operations	X	X	X	
8. A description of the system for maintaining records as required under § 139.301	X	X	X	X
9. A description of personnel training as required under § 139.303	X	X	X	X
10. Procedures for maintaining the paved areas as required under § 139.305	X	X	X	X
11. Procedures for maintaining the unpaved areas as required under § 139.307	X	X	X	X
12. Procedures for maintaining the safety areas as required under § 139.309	X	X	X	X
13. A plan showing the runway and taxiway identification system along with the location and inscription of the signs as required under § 139.311	X	X	X	X
14. A description of, and procedures for maintaining, the marking, signs, and lighting systems as required under 139.311	X	X	X	X
15. A snow and ice control plan as required under § 139.313	X	X	X	
16. A description of the facilities, equipment, personnel, and procedures for meeting the rescue and firefighting requirements in accordance with §§ 139.317 and 139.319	X	X	X	X
17. A description of any approved exemption to rescue and firefighting requirements as authorized under § 139.321	X	X	X	X
18. Procedures for handling fuel, lubricants and oxygen required under § 139.323	X	X	X	X
19. A description of, and procedures for maintaining, the traffic and wind direction indicators as required under § 139.325	X	X	X	X
20. An emergency plan as required under § 139.327	X	X	X	X
21. Procedures for conducting the self-inspection program as required under § 139.329	X	X	X	X
22. Procedures for controlling ground vehicles as required under § 139.331	X	X	X	
23. Procedures for obstruction removal, marking, or lighting as requried under § 139.333	X	X	X	
24. Procedures for protection of navaids as required under § 139.335	X	X	X	
25. A description of public protection as required under § 139.337	X	X	X	
26. A wildlife hazard management plan as required under § 139.339	X	X	X	
27. Procedures for airport condition reporting as required under § 139.341	X	X	X	X
28. Procedures for identifying, marking, and reporting construction and other unserviceable areas as required under § 139.343	X	X	X	
29. Any other item that the Administrator finds is necessary to ensure safety in air transportation	X	X	X	X

Issued in Washington, DC, on August 9, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

[FR Doc. 01–20518 Filed 8–14–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 97P–0210]

Ear, Nose, and Throat Devices; Reclassification of Endolymphatic Shunt Tube With Valve

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the endolymphatic shunt tube with valve from class III to class II. The device is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease. This reclassification is based upon new information regarding the device contained in a reclassification petition submitted by E. Benson Hood Laboratories, Inc. (Hood Laboratories). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final. 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 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments by November 13, 2001. See section XII for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: James K. Kane, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory authorities)

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, depending on 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, 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 prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA 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) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' to support reclassification under section 513(e) of the act must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., nonpublic information in a pending PMA. (See section 520c of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Device

In the **Federal Register** of November 6, 1986 (51 FR40378), FDA issued a final rule classifying the endolymphatic shunt tube with valve into class III (21 CFR 874.3850). The preamble to the proposal to classify the device (47 FR 3280, January 22, 1982) included the